Calendar No. 155

100TH CONGRESS
1st Session

SENATE

REPORT
100-83

PROCESS PATENTS AMENDMENTS ACT OF 1987

JUNE 23, 1987.—Ordered to be printed

Mr. BIDEN, from the Committee on the Judiciary,
submitted the following

REPORT

[To accompany S. 1200]

The Committee on Judiciary, to which was referred the bill (S. 1200) to amend Title 35, United States Code, with respect to patented processes, patent misuse and licensee challenges to patent validity, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE

The purpose of the proposed legislation, as amended, is to improve the rights of patent owners and certain aspects of the patent law by providing patent owners the new right to sue for damages and seek an injunction in Federal district court when someone, without authorization, uses or sells in the United States, or imports into the United States a product made by their patented process; by reforming the doctrine of patent misuse so it will not be used to restrict the rights of patent owners when their licensing practices do not violate the antitrust laws; by clarifying the rights of parties with respect to patent licensing agreements; and by extending the patent on the pharmaceutical product gemfibrozil for a period of 5 years.

II. TEXT OF BILL

Calendar No. 155

100TH CONGRESS
1ST SESSION

S. 1200

To amend title 35, United States Code, with respect to patented processes, patent misuse and licensee challenges to patent validity.

IN THE SENATE OF THE UNITED STATES

MAY 14 (legislative day, MAY 13), 1987

Mr. DECONCINI (for himself, Mr. HATCH, and Mr. LAUTENBERG) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

JUNE 5, 1987

Reported by Mr. BYRD (for Mr. BIDEN), with an amendment and amendment to the title

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend title 35, United States Code, with respect to patented processes, patent misuse and licensee challenges to patent validity.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~TITLE I—PROCESS PATENT AMENDMENTS ACT OF 1987~~

~~SECTION 1. SHORT TITLE.~~

~~That this Act may be cited as the "Process Patent Amendments Act of 1987".~~

~~SEC. 2. RIGHTS OF OWNERS OF PATENTED PROCESSES.~~

~~Section 154 is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,".~~

~~SEC. 3. INFRINGEMENT FOR IMPORTATION, SALE, OR USE.~~

~~Section 271 is amended by adding at the end the following new subsection:~~

~~"(g) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A prod-~~

~~uct which is made by a patented process will, for purposes of this title, not be considered to be so made after—~~

~~"(1) it is materially changed by subsequent processes; or~~

~~"(2) it becomes a minor or nonessential component of another product.".~~

~~**SEC. 4. DAMAGES FOR INFRINGEMENT.**~~

~~(a) LIMITATIONS AND OTHER REMEDIES.—Section 287 is amended—~~

~~(1) in the section heading by striking "**Limitation on damages**" and inserting "**Limitation on damages and other remedies**";~~

~~(2) by inserting "(a)" before "Patentees"; and~~

~~(3) by adding at the end the following:~~

~~"(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 6 of the Process Patent Amendments Act of 1987. The modifications of remedies provided in this subsection shall not be available to any person who—~~

~~"(A) practiced the patented process;~~

~~"(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or~~

~~"(C) had knowledge before the infringement that a patented process was used to make the product the~~

~~importation, use, or sale of which constitutes the infringement.~~

~~"(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to the infringer, or which the infringer has made a binding commitment to purchase and which has been partially or wholly manufactured, before the infringer had notice of infringement as defined in paragraph (5). The infringer shall bear the burden of proving any such possession, transit, binding commitment or manufacture. If the court finds that (i) the infringer maintained or ordered an abnormally large amount of infringing product, or (ii) the product was acquired or ordered by the infringer to take advantage of the limitation on remedies provided by this paragraph, the court shall limit the application of this paragraph to that portion of the product supply which is not subject to such a finding.~~

~~"(3)(A) In making a determination with respect to remedy in an action brought for infringement under section 271(g), the court shall consider—~~

~~"(i) the good faith and reasonable business practices demonstrated by the defendant;~~

~~"(ii) the good faith demonstrated by the plaintiff with respect to the request for disclosure as provided in paragraph (4); and~~

~~“(iii) the need to restore the exclusive rights secured by the patent.~~

~~“(B) For purposes of paragraph (3)(A), the following are evidence of good faith—a request for disclosure by a party, a response by the party receiving the request for disclosure within sixty days, and submission of the response by the party who received the disclosed information to the manufacturer, or if not known, the supplier with a request for a written statement that the process claimed in the disclosed patent is not used. The failure to perform any such acts is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances shall include the case in which, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.~~

~~“(4) For purposes of paragraph (3), a ‘request for disclosure’ means a written request made to a party then engaged in the manufacture of a product to identify all process patents owned by or licensed to the party as of the time of the request that the party then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request—~~

~~“(i) made by a party regularly engaged in the United States in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products in the United States;~~

~~“(ii) made prior to such party's first importation, use or sale of units of the product produced by an infringing process and prior to notice of infringement; and~~

~~“(iii) which includes a representation by the requesting party that it will promptly submit the patents identified to the manufacturer, or if not known, the supplier of the product to be purchased by the requestor and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.~~

~~“(5)(A) For the purposes of this subsection, notice of infringement means actual knowledge, or receipt by a party of a written notification or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that the product was made by an infringing process and not by a noninfringing process.~~

~~"(B) A written notification from the patent holder charging a party with infringement shall, in order to be a valid notification under paragraph (A), specify the patent alleged to have been used and the reasons for belief that such process, and not others, was used in the production of the product.~~

~~"(C) A party who receives a notification as described in (B) and fails to thereafter seek information from the manufacturer, or if not known, the supplier as to whether the allegations in the statement are true shall, absent mitigating circumstances, be deemed to have notice of infringement.~~

~~"(D) A party who fails to make the submission referred to in subsection (b)(4)(iii) shall be deemed to have notice of infringement.~~

~~"(E) Filing of an action for infrangement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of (A).".~~

~~(b) TECHNICAL AMENDMENT.—The item relating to section 287 in the table of sections for chapter 29 is amended to read as follows:~~

~~"287. Limitations on damages and other remedies; marking and notice.".~~

~~SEC. 5. PRESUMPTION IN INFRINGEMENT ACTIONS.~~

~~(a) IN GENERAL.—Chapter 29 is amended by adding at the end the following:~~

~~"§ 295. Presumption: Product made by patented process~~

~~"In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds—~~

~~"(1) that there is evidence establishing a substantial likelihood that the product was made by the patented process; and~~

~~"(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine,~~

~~the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.".~~

~~(b) Conforming Amendment.—The table of sections for chapter 29 is amended by adding after the item relating to section 294 the following:~~

~~"295. Presumption: Product made by patented process.".~~

~~**SEC. 6. EFFECTIVE DATE.**~~

~~(a)(1) In General.—The amendments made by this title shall apply only to products made or imported after the date of the enactment of this Act.~~

~~(2) Exceptions.—This Act shall not abridge or affect the right of any person or any successor in business of such~~

~~person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on May 15, 1987, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This paragraph shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a patent process enforcement action commenced before January 1, 1987, including actions before the International Trade Commission, that is pending or in which an order has been entered.~~

~~(b) RETENTION OF OTHER REMEDIES.—The amendments made by this title shall not deprive a patent owner of any remedies available under subsection (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.~~

~~SEC. 7. REPORTS TO CONGRESS.~~

~~(a) CONTENTS.—The Secretary of Commerce shall, not later than the end of each one-year period described in subsection (b), report to the Congress on the effect of the amendments made by this title on the importation of ingredients to be used for manufacturing products in the United States in~~

~~those domestic industries that submit complaints to the Department of Commerce, during that one-year period, alleging that their legitimate sources of supply have been adversely affected by the amendments made by this title.~~

~~(b) WHEN SUBMITTED.—A report described in subsection (a) shall be submitted with respect to each of the five one-year periods which occur successively beginning on the date of the enactment of this Act and ending five years after that date.~~

~~TITLE II—PATENT MISUSE DOCTRINE REFORM~~

~~Section 271 of title 35, United States Code, is amended—~~

~~(1) by redesignating subsection (c) as paragraph (1) of subsection (c);~~

~~(2) by redesignating subsection (d) as paragraph (2) of subsection (c); and~~

~~(3) by inserting after subsection (d) the following new subsection:~~

~~"(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions, in view of the circumstances in~~

~~which such practices or actions are employed, violate the antitrust laws.".~~

~~TITLE III—LICENSEE CHALLENGES TO PATENT VALIDITY~~

~~SEC. 301. Chapter 29 of title 35, United States Code, is amended by adding at the end thereof the following new section:~~

~~"§ 295. Licensee challenges to patent validity~~

~~"(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent for which the licensee has obtained a license. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.~~

~~"(b) Any patent license agreement may provide for a party or parties to the agreement to terminate the license if the licensee asserts in a judicial action the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached or until the license is terminated. Such agreement shall not be unenforceable as to such provisions on the grounds that such provisions are contrary to Federal law or policy.".~~

~~SEC. 302. The table of sections for chapter 29 of title 35, United States Code is amended by adding at the end thereof the following new item:~~

~~"205. Licensee challenges to patent validity.".~~

That this Act may be cited as the "Process Patent Amendments Act of 1987".

TITLE I—PROCESS PATENT AMENDMENTS ACT OF 1987

SEC. 101. RIGHTS OF OWNERS OF PATENTED PROCESSES.

Section 154 of title 35, United States Code, is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,".

SEC. 102. INFRINGEMENT FOR IMPORTATION, SALE, OR USE.

Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(g) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of

the importation or other use or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

"(1) it is materially changed by subsequent processes; or

"(2) it becomes a trivial and nonessential component of another product.".

SEC. 103. DAMAGES FOR INFRINGEMENT.

(a) LIMITATIONS AND OTHER REMEDIES.—Section 287 of title 35, United States Code, is amended—

(1) in the section heading, by striking "LIMITATION ON DAMAGES" and inserting "LIMITATION ON DAMAGES AND OTHER REMEDIES";

(2) by inserting "(a)" before "Patentees"; and

(3) by adding at the end the following:

"(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 105 of the Process Patent Amendments Act of 1987. The modifications of remedies provided in this subsection shall not be available to any person who—

"(A) practiced the patented process;

"(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

"(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.

"(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to the party, or which the party has made a binding commitment to purchase and which has been partially or wholly manufactured, before the party had notice of infringement as defined in paragraph (5). The party shall bear the burden of proving any such possession, transit, binding commitment, or manufacture. If the court finds that (A) the party maintained or ordered an abnormally large amount of infringing product, or (B) the product was acquired or ordered by the party to take advantage of the limitation on remedies provided by this paragraph, the court shall limit the application of this paragraph to that portion of the product supply which is not subject to such a finding.

"(3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider—

"(i) the good faith and reasonable business practices demonstrated by the defendant,

"(ii) the good faith demonstrated by the plaintiff with respect to the request for disclosure as provided in paragraph (4), and

"(iii) the need to restore the exclusive rights secured by the patent.

"(B) For purposes of subparagraph (A), the following are evidence of good faith: a request for disclosure by a party, a response by the party receiving the request for disclosure within 60 days, and submission of the response by the party who received the disclosed information to the manufacturer, or if not known, the supplier with a request for a written statement that the process claimed in the disclosed patent is not used. The failure to perform any such acts is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances shall include the case in which, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

"(4) For purposes of paragraph (3), a 'request for disclosure' means a written request made to a party then engaged in the manufacture of a product to identify all process patents owned by or licensed to the party as of the time of the request that the party then reasonably believes could be asserted to be infringed under section 271(g) if that product

were imported into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request—

"(A) made by a party regularly engaged in the United States in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products in the United States;

"(B) made prior to such party's first importation, use, or sale of units of the product produced by an infringing process and prior to notice of infringement; and

"(C) which includes a representation by the requesting party that it will promptly submit the patents identified to the manufacturer, or if not known, the supplier of the product to be purchased by the requestor, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

"(5)(A) For the purpose of this subsection, notice of infringement means actual knowledge, or receipt by a party of a written notification, or a combination thereof, of informa-

tion sufficient to persuade a reasonable person that it is likely that a product was made by a patented process.

"(B) A written notification from the patent holder charging a party with infringement shall specify the patent alleged to have been used and the reasons for a good faith belief that such process was used. If the patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

"(C) A party who receives a written notification as described in the first sentence of such subparagraph (B) and fails to thereafter seek information from the manufacturer, or if not known, the supplier, as to whether the allegations in the notification are true shall, absent mitigating circumstances, be deemed to have notice of infringement. This provision shall apply even though the notification does not establish notice of infringement under subparagraph (A).

"(D) A party who fails to make the submission referred to in subsection (b)(4)(C) shall be deemed to have notice of infringement.

"(E) Filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A).".

(b) TECHNICAL AMENDMENT.—The item relating to section 287 of title 35, United States Code, in the table of sections for chapter 29 of such title is amended to read as follows:

"287. Limitations on damages and other remedies; marking and notice.".

SEC. 104. PRESUMPTION IN INFRINGEMENT ACTIONS.

(a) IN GENERAL.—Chapter 29 of title 35, United States Code, is amended by adding at the end the following:

"§ 295. Presumption: Product made by patented process

"In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds—

"(1) that there is evidence establishing a substantial likelihood that the product was made by the patented process, and

"(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the *process shall be on the party asserting that it was not so made.".*

(b) Conforming Amendment.—The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product made by patented process.".

SEC. 105. EFFECTIVE DATE.

(a)(1) In General.—The amendments made by this title shall apply only to products made or imported after the date of the enactment of this Act.

(2) Exceptions.—This title shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on May 15, 1987, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This paragraph shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a patent process enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

(b) R*ETENTION OF* O*THER* R*EMEDIES*.—*The amendments made by this title shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.*

SEC. 106. REPORTS TO CONGRESS.

(a) C*ONTENTS*.—*The Secretary of Commerce shall, not later than the end of each 1-year period described in subsection (b), report to the Congress on the effect of the amendments made by this title on the importation of ingredients to be used for manufacturing products in the United States in those domestic industries that submit complaints to the Department of Commerce, during that 1-year period, alleging that their legitimate sources of supply have been adversely affected by the amendments made by this title.*

(b) W*HEN* S*UBMITTED*.—*A report described in subsection (a) shall be submitted with respect to each of the five 1-year periods which occur successively beginning on the date of the enactment of this Act and ending five years after that date.*

TITLE II—PATENT MISUSE DOCTRINE REFORM

SEC. 201. INFRINGEMENT OF PATENT.

Section 271 of title 35, United States Code, is amended—

(1) by redesignating subsection (c) as subsection (c)(1) of subsection (c);

(2) by redesignating subsection (d) as paragraph (2) of such subsection (c); and

(3) by inserting after subsection (c) the following new subsection:

"(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions or inactions, in view of the circumstances in which such practices or actions or inactions are employed, violate the antitrust laws.".

TITLE III—LICENSEE CHALLENGES TO PATENT VALIDITY

SEC. 301. LICENSEE CHALLENGES.

(a) IN GENERAL.—Chapter 29 of title 35, United States Code, as amended by section 104 of this Act, is fur-

ther amended by adding at the end thereof the following new section:

"§ 296. Licensee challenges to patent validity

"(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent for which the licensee has obtained a license. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

"(b) Any patent license agreement may provide for a party or parties to the agreement to terminate the license if the licensee asserts, in a judicial action, the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached or until the license is terminated. Such agreement shall not be unenforceable as to such provisions on the grounds that such provisions are contrary to Federal law or policy.".

(b) TECHNICAL AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, as amended by section 104 of this Act, is further amended by adding at the end thereof the following new item:

"296. Licensee challenges to patent validity.".

TITLE IV—PHARMACEUTICAL PATENT TERM RESTORATION ACT AMENDMENTS

SEC. 401. (a) Title 35, United States Code, is amended by adding the following new section:

"§ 155B. Patent Term Restoration

"(a) Notwithstanding section 154 of this title, the term of a patent which encompasses within its scope a composition of matter which is a new drug shall be extended for a period of 5 years, and such patent shall have the effect as if originally issued with such extended term, if—

"(1) such composition has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act,

"(2) the Federal Food and Drug Administration has approved a new drug application after receipt of a letter from the applicant stating that a Phase IV clinical study that had been requested as a condition for approval has been undertaken,

"(3) the Phase IV clinical study has covered at least 5 years with the study term commencing prior to the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984 and ending subsequent to the enactment of such Act,

"(4) such Phase IV clinical study has been completed, and a supplemental new drug application to expand the permitted indications and usage in the labeling of the new drug based upon such Phase IV clinical study has been submitted to the Federal Food and Drug Administration,

"(5) the Federal Food and Drug Administration has either approved the supplemental new drug application or the original patent term is within 90 days of expiration, and

"(6) the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved.

If, however, the term of a patent is extended because the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved prior to 90 days before the expiration of the patent, such patent extension shall immediately terminate if the Federal Food and Drug Administration makes a final determination disapproving the supplemental new drug application.

"(b)(1) The patentee, his heirs, successors, or assigns shall notify the Commissioner of Patents and Trademarks within 30 days after the date of enactment of this section, or

within 30 days after the date of the approval of the supplemental new drug application if such approval does not occur before enactment of this section, or within 30 days after the date which is 90 days from the expiration of the original patent term if the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved by such date, of the number of the patent to be extended.

"(2) On receipt of such notice, the Commissioner shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter to which such extension is applicable. Such certificate shall be recorded in the official file of the patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office. If, subsequent to a notification that it is within 90 days of the expiration of the patent and that the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved, a final determination is made by the Federal Food and Drug Administration that the supplemental new drug application is disapproved, the patentee, his heirs, successors, or assigns shall, within 2 days, notify the Commissioner of Patents and

Trademarks of such final determination. On receipt of such notice and if the patent has been extended pursuant to the terms hereof, the Commissioner shall promptly issue a certificate of termination of extension, under seal, stating the fact that the patent is terminated, effective the date of the final determination that the supplemental new drug application is disapproved, and identifying the composition of matter to which such termination of extension is applicable. Such certificate shall be recorded in the official file of the patent terminated and such certificate shall be considered as a part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.".

(b) The analysis for chapter 14 of such title 35 is amended by adding at the end the following:

"155B. Patent term restoration.".

Amend the title to read as follows: "A bill to amend title 35, United States Code, with respect to patented processes, patent misuse, license challenges to patent validity, and patent term restoration.".

III. TITLE I—PROCESS PATENT AMENDMENTS ACT OF 1987

A. Purpose of Amendment

As amended, title I of S. 1200 provides patent owners the new right to sue for damages and seek an injunction in Federal district court when someone, without authorization, uses or sells in the United States, or imports into the United States a product made by their patented process.

B. History of Legislation

The importance of strengthening process patent protection was first recognized in 1966 by President Johnson's Commission on the Patent System; then in 1979 by President Carter's Domestic Policy Review on Industrial Innovation, and again in 1985 by President Reagan's Commission on Industrial Competitiveness. More recently, it was included in President Reagan's competitiveness initiative of 1987 and strongly endorsed by the President's Commission on Industrial Competitiveness in 1984.

The Process Patent Amendments Act of 1987, title I of S. 1200, is the result of a carefully crafted compromise reached between Senators DeConcini, Hatch, Lautenberg and a wide variety of parties interested in process patent legislation. On April 22, 1987, the Patents, Copyrights and Trademarks Subcommittee held a hearing on predecessors to this bill, S. 568, which was introduced in the 100th Congress by Senators Hatch and DeConcini and S. 573, which was introduced by Senator Lautenberg. Hearings on Process Patent legislation was also held in both the 98th and 99th Congresses. S. 568 contained the same language as S. 1543, which passed the Judiciary Committee and the Senate unanimously during the 99th Congress. On May 13, 1987 the Patents Subcommittee reported S. 568 with an amendment in the nature of a substitute which was then introduced as title I of S. 1200 on May 14, 1987 by Senators DeConcini, Hatch, and Lautenberg. S. 1200 as amended passed the Judiciary Committee unanimously on June 4, 1987. The Judiciary Committee will include S. 1200 in the Senate Omnibus Trade Act of 1987.

C. Discussion

America's leading position in technology innovation throughout the world is credited in large part to the stimulus of its patent system, which stems ultimately from Article I, Section 8, clause 8 of the Constitution which states, "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . ." In the past two decades, however, it has become necessary to modernize our patent laws. As compared with those of our major trading partners, the inadequate protection contained in U.S. process patent law has emerged as a major factor in the dynamics of global innovation and economic competition. In contrast to Japan and nearly all of the Western European nations, the United States does not provide patent protection against the importation, and subsequent use or sale, of products made abroad without authorization using a process patented in the United States except for a limited form of protection is afforded under the trade laws (19 U.S.C. 1337a) enforced by the International Trade Commission (ITC).

The U.S. patent laws recognize three basic types of inventions for which patents may be obtained: products, methods of use, and methods of manufacture. Patents on the last are also known as process patents, that is, patents on process inventions. A process patent covers a process for making a product, which may or may not be patented itself. Process patents promise to be increasingly important to a number of industries in the coming years, especially in the areas of industrial and pharmaceutical chemicals, optical fibres, and above all in the fields of biotechnology and bioengineering research. Biotechnology companies are often built around a new process for artificial manufacture of a substance that occurs in nature and is therefore itself unpatentable. A well known example is the Genentech Corporation of California, whose principal assets since its founding in 1976 have been process patents on revolutionary new ways of making human insulin and growth hormone.

Under our current patent laws, a patent on a process gives the patentholder the right to exclude others from using that process in the United States without authorization from the patentholder. The other two standard aspects of the patent right—the exclusive right to make or sell the invention—are not directly applicable to a patented process. S. 1200 proposes to also cover the importation, use or sale in the United States of products resulting from the process. The bill does not attempt to prevent the use of the process in another country. If the U.S. process patentholder has not obtained a similar patent in the other country, he has no right by virtue of his U.S. patent to prevent anyone from using the process in that country. However, if the U.S. patentholder does have a patent in the other country as well, he may seek remedy in the courts of that country. S. 1200 would protect against the entry into the U.S. marketplace of goods made abroad without authorization from the inventor who has a process patent in this country. The patent is on the process alone, but the entry of the goods made elsewhere by that process clearly encroaches on the rights of the patent owner.

The principle of process patent protection is also incorporated in the European Patent Convention, the Community Patent Convention, and the World Intellectual Property Organization (W.I.P.O.) Treaty on Harmonization. The following excerpt from a recent memorandum on process patent law prepared by the International Bureau of W.I.P.O. elaborates on the rationale for including products obtained from a patented process in the scope of the protection afforded by the process patent:

> The extension (to the product of the process) seems to be an exception to the principle that the protection conferred by a patent or another title of protection for an invention is defined by the object of the invention. In the case of a process invention, a strict application of the said principle would mean that the owner of a process patent could only exclude others from using the patented process. The legal

provisions which extend process protection to products obtained by the patented process are based on practical economic considerations. A process which leads to a specific product presents an economic value only through the product. However, it is not always possible to obtain a patent for the product; for example, the product may not be new or may—although new—lack inventive step. The invention of a new and inventive process for the production of such a product which is not patentable constitutes an important technological advance but the reward granted through a process patent is not important because—without an extension to the product—the process patent would be difficult to enforce (since infringement of the process is difficult to prove) and could even be circumvented by use of the process in another country where the process is protected. In order to make patent protection of a process meaningful, it is therefore necessary to consider the patented process and the resulting product as a whole, with the consequence that process protection is automatically extended to the resulting product even if the said product has not been claimed.[1]

FOREIGN PROCESS PATENT LEGISLATION

Importation, use and sale in the United States of products produced by processes patented in this country severely diminishes the value of such patents. This practice must be effectively countered by changes in the patent laws to protect the legitimate interests of U.S. inventors. Expanding the scope of our laws to bring them into conformity with the European Patent Convention and the national laws of many industrialized countries is necessary to protect the continued growth of American business. The following chart summarizes the protection offered to process patent holders in the group B or development market economy countries. In addition, some typical examples of foreign laws in this area are helpful for comparison. As the chart and summaries indicate, most countries' patent laws are structured so that the direct product of a patented process is also included within the scope of the patent. Nearly one-half of those countries make importation an act of infringement.

[Charts and summaries follow:]

PROCESS PATENT PROTECTION IN GROUP B COUNTRIES

Country	Process patent protects its direct product	Importation constitutes infringement	Presumption in favor of process patentee
Austria [1]	Yes		Yes.[2]
Belgium [1]	Yes [3] [4]	Yes	
Canada	Yes [3] [4]		Yes.[2] [4]
Cyprus [5]	Yes	Yes	
Denmark	Yes	Yes	
Finland	Yes	Yes	
France [1]	Yes	Yes	

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[1] "Extension of Patent Protection of a Process to the Products obtained by that Process; Proof of Infringement of a Process Patent." Memorandum by the International Bureau of WIPO, March 12, 1986, pp. 3-4.

PROCESS PATENT PROTECTION IN GROUP B COUNTRIES—Continued

Country	Process patent protects its direct product	Importation constitutes infringement	Presumption in favor of process patentee
Federal Republic of Germany [1]	Yes		Yes.[2]
Great Britain [1]	Yes	Yes	
Greece	Yes	Yes	Yes.[2]
Holy See [6]			
Iceland	Yes	Yes	
Ireland	Unclear [3] [7]		
Italy [1]	Yes		Yes.[2]
Japan	Yes	Yes	Yes.
Liechtenstein [1] [8]	Yes		Yes.
Luxembourg [1] [9]	Yes [4]		
Monaco [6]			
Netherlands [1]	Yes		Yes.[2]
New Zealand	Yes [4]		
Norway	Yes	Yes	
Portugal	Yes	Yes	
San Marino [10]	Yes		Yes.[2]
South Africa	Yes		Yes.
Spain	Yes	Yes	
Sweden [1]	Yes	Yes	Yes.[2]
Switzerland [1]	Yes		Yes.
Turkey [9]			
United States of America			

[1] EPC member.
[2] Applies to new substances only.
[3] No clear statutory provision.
[4] Apparently applies in at least some situations.
[5] Registration in Cyprus of a United Kingdom patent confers the same right in Cyprus.
[6] No patent law.
[7] Claims are permitted, but legal issues are apparently unsettled.
[8] Liechtenstein and Switzerland constitute a single territory for patent purposes.
[9] No copy of the national law was available.
[10] Industrial property rights acquired in Italy are valid in San Marino and vice versa.

DENMARK

SECTION 3

(1) The exclusive right conferred by a patent shall imply that no one except the proprietor of the patent may without permission exploit the invention:

(i) by making, offering, putting on the market or using a product which is the subject-matter of the patent, or by importing or stocking the product for these purposes;

(ii) by using a process which is the subject-matter of the patent or by offering the process for use in this country if the person offering the process knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent;

(iii) by offering, putting on the market or using a product obtained by a process which is the subject-matter of the patent or by importing or stocking the product for these purposes.

FRANCE

CHAPTER THREE.—RIGHTS AND OBLIGATIONS ATTACHED TO THE PATENT

Article 28.—1. The scope of protection conferred by a patent shall be determined by the terms of the claims. The description of the invention and the drawings, however, shall serve to construe the claims.

2. Where a patent relates to a process, the protection conferred by the patent shall extend to the products directly obtained by that process.

Article 29.—A patent confers the right to prohibit any other person, without the consent of the proprietor of the patent:

(a) from making, offering, putting on the market, using, or importing or storing for such purposes the product to which the patent relates;

(b) from using a process to which the patent relates, or, where such other person knows, or where it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within French territory;

(c) from offering, putting on the market, using, or importing or storing for such purposes the product obtained directly by the process to which the patent relates.

GREAT BRITAIN

STATUTES, REGULATIONS, AND TREATIES

Patents Act 1977

Infringement

60.—(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say—

(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

(b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;

(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

§ 5.—No-one may make an occupation of the following without the consent of the patentee:—1. Manufacturing, importing or offering for sale an article which is patented or prepared by a patented method; or 2. Using the patented method.—The following is however, permissible having no regard for a Patent:—a) The use of articles accompanying or connected with means of transport from other countries when these come to this country for limited periods, and b) The continued use of articles arrived by and belonging to means of transport which have been purchased abroad for Icelandic currency or for an Icelandic vessel which has broken down at sea and been repaired abroad.

ITALY

§ 2.—The patent concerning a new industrial method or process confers upon the patentee the exclusive use thereof.

The exclusive use includes also commercializing the product directly obtained by the new industrial method or process. If the product is a new one, every identical product is presumed to have been obtained, unless there is evidence to the contrary, but the method or process which is the subject of the patent.

JAPAN

3. "Working" in respect of an invention in this Law shall mean the following acts:

(1) In an invention of a thing, acts of manufacturing, using, transferring, leasing, exhibiting for the purpose of transfer or lease, or importing the thing;

(2) In an invention of a process, acts of using the process.

(3) In an invention of a process of manufacturing a thing, acts of using, transferring, leasing, exhibiting for the purpose of transfer or leave, or importing the thing produced by the process in addition to those as mentioned in the preceding items.

PORTUGAL

Article 214. A penalty of 500 to 10,000 escudos, to which may be added imprisonment for a period of from one to six months, will be imposed on those who, during the period of legal protection, should prejudice the owner of a patent in the exercise of his right in any of the following ways:

1. Manufacturing, without license from the title holder, the articles or products covered by the patent;
2. Employing, without the said license, the means and processes or using new applications of means and processes forming the subject of the patent;
3. Importing, selling, offering for sale, putting in circulation or concealing, in bad faith, products obtained in any of the ways referred to.

SWEDEN

SECTION 3

The exclusive right conferred by a patent implies, with the exceptions stated below, that no one except the proprietor of the patent may, without the proprietor's consent, use the invention by

(1) making, offering, putting on the market or using a product protected by the patent or importing or possessing such product for these purposes;

(2) using a process which is protected by the patent or, while knowing, or it being obvious from the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use in this country;

(3) offering, putting on the market, or using products made by a process protected by the patent or importing or possessing the product for these purposes.

SWITZERLAND

If the invention concerns a process, the effects of the patent shall extend to the immediate products of the process.

SECTION 67

If the invention concerns a process for the manufacture of a new product, every product of the same composition shall be presumed to have been made by the patented process until proof to the contrary has been adduced.

Subsection 1 shall apply by analogy in the case of a process for the manufacture of a known product if the patentee shows prima facie evidence of infringement of the patent.

WEST GERMANY

PART NINE.—INFRINGEMENT OF PATENT

Article 74

(1) A person who uses an invention contrary to the provisions of Articles 6, 7 and 8 may be sued by the injured party to enjoin such use.

(2) A person making such use intentionally or negligently shall be liable for compensation to the injured party for the damage suffered therefrom. If the infringer has acted with only slight negligence, the court may fix, in lieu of compensation, an indemnity being between the damage to the injured party and the profit which has accrued to the infringer.

(3) In the case of an invention whose subject matter is a process for the production of a new substance, any substance of the same nature shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

NEED FOR MODERNIZATION OF U.S. PROCESS PATENT LAW

The United States has historically given different treatment to product and process patents, while so many other industrialized countries give uniform, full protection to both. The Commissioner of Patents and Trademarks, Donald Quigg, has suggested that the U.S. patent system is older than many of the European systems and that the ultimate historical origin of the omission of process patent protection may have been simply that in earlier commercial eras processes had not become so significant as they are in the present high-technology milieu. At the same time, adjacent European countries would become more aware more quickly of importations of products made outside by processes patented in the receiving country.

Many industrial countries, Japan and Germany for example, have only recently adopted product patent protection in the pharmaceutical area, having previously confined patent protection on drugs to the processes used to make them, in the interest of promoting wider and easier availability of medicines for their populations. Thus when a new medicine comes on the market, competitors would only have to find a new way to produce it and could go on the market immediately, without waiting for any patent on the medicine itself to expire. Because it was the only form of protection allowed for pharmaceutical products, broader process patent protection was developed in those countries, covering not only domestic use of the process, but also importation, use or sale of the products obtained from the process. On the other hand, when Germany and Japan (in 1967 and 1975 respectively) broadened their laws to cover pharmaceutical product patents, they did not eliminate patent protection of processes and their resulting products.

Most countries that provide process patent protection extending to the products have also established a rebuttable presumption shifting the burden of proof to the defendant if the plantiff presents evidence meeting some threshold of reasonable likelihood that the product was made by the patented process (France and Sweden are the only exceptions). However, many of these countries add a limitation that this presumption is only available in the case of processes for making "new" products. By contrast, as discussed further below and in the sectional analysis, S. 1200 allows the rebuttable presumption in any process patent infringement action under the bill, on the theory that every genuinely novel and useful (hence patentable) process invention deserves the full protection of the law, regardless of whether the resulting product is new or not. The example of the biotechnology industry is relevant here, in its efforts to develop recombinant DNA processes to produce already existing natural substances such as growth hormones. Another point of difference, again discussed at length below, is the limitation in the process patent laws of most industrialized nations to products made "directly" from the process; Japan and Sweden are the only exceptions to this rule. S. 1200 introduces a new phrase, "materially changed by subsequent processes; or . . . becomes a trivial and nonessential component of another product," to serve the same general purpose of restricting the scope of the bill to exclude ultimate products that, because of intervening manufacturing steps, cease to have a reasonable nexus with the patented process.

An integral part of the debate on strengthening U.S. process patent protection has been the alternative remedy under the trade laws against importation of products made abroad using a process patented in the United States (Section 337a of the Tariff Act of 1930, 19 U.S.C. 1337a). Section 337 originated in 1922 as an antidote to a range of unfair methods of competition in import trade. It was not widely used until the 1974 strengthening amendments providing for more timely and effective remedies, the principal change being that the ITC was given full authority to order remedies, subject only to veto by the President for policy reasons. In process patent cases brought before the ITC, the available remedies under section 337a are exclusion of the goods from entry, and, if the goods have already entered, cease and desist orders against particular firms that have received them.

In order to obtain these remedies from the ITC, the complainants must show that their patented processes were used in manufacturing the imported products, that an efficiently and economically operated industry utilizing the patent exists in the United States, and that the imported product had the effect or tendency of destroying or substantially injuring the domestic industry. After making these findings, the ITC must in addition decide that enjoining the importation of the infringing goods is in the public interest. Only then can the ITC provide relief to the process patentholder; and even then, its decision is subject to a binding Presidential veto.

The ITC, unlike a Federal court in a patent infringement suit, can award no damages. Payment of damages to the patentholder has the effect of compensating inventors and penalizing infringers for the economic injury due to the infringement, and also acts as a deterrent against future infringements. Furthermore, the tests that must be met to win an ITC order excluding the infringing products are more elaborate than in a Federal court action where all that is necessary is to show infringement. The requirement in the ITC proceeding to show that the importation of infringing goods is causing substantial injury to an efficiently run domestic industry requires the patentowner to show more than infringement. The patentee must show that there is an industry in the United States which generally means that the patentholder must practice a patented process commercially in the United States before he may enforce it. Morever, the industry must be efficiently and economically operated. The patentee also must show sufficent harm to justify relief. These requirements utilize an approach that has never been a part of our patent system. Instead, our system is based on the conviction that the public is well served by the disclosure of the invention in return for a limited period of the exclusivity for the inventor, even if the latter chooses not to commercialize the invention during this period.

A hypothetical example illustrates this difference. Suppose an American company has obtained a process patent. The issued patent discloses the details of its new process for all the world to see. But for one reason or another, the American company has not yet been able to begin marketing the product. In that situation, the company may be unable to prove the existence of establishment of a domestic industry, and therefore unable to stop foreign pirates who use the published process and import the resulting products for sale in this country. A similar predicament might beset a university that obtains a process patent but is still involved in negotiations with potential licensees. To be sure, there may be some scope in a Section 337 investigation for treating impairment for prevention of a domestic patentholder's efforts to establish an industry here as substantial injury. But this whole issue simply does not arise in an ordinary infringement suit under the patent laws, where the only question is whether a valid patent has been infringed.

Even where the process patent has engendered an efficiently run domestic industry, the patentholder has the additional burden of showing that the industry has been injured by the entry of infringing articles. This circumstance was illustrated in the recent *Corning* case against Sumitomo before the ITC (In the Matter of Certain Optical Waveguide Fibers; Investigation No. 337-TA-189). Corning succeeded in establishing that its patents were valid and were being infringed by Sumitomo's imported products. Further, it proved that two legitimate domestic industries, efficiently and economically operated, had grown under the Corning patents. However, because the ITC found that Sumitomo's infringing imports did not substantially injure either of those domestic industries, it found no violation of Section 337, and Corning was unable to obtain any relief.

Finally, in the best of circumstances, where the full ITC remedy is obtained, the patentholder is saddled with an expensive and burdensome proceeding, with no prospect of having his injury compensated, only brought to a hold prospectively. By the same token, the ITC remedy has little deterrent value. Foreign manufacturers are not punished for simply infringing U.S. process patents by importing their products into the country until they are enjoined, with no further penalty. Still, the ITC forum will remain a useful supplement in process patent infringement situations after S. 1200 is enacted. The ITC can provide speedy and comprehensive injunctive relief (covering many ports of entry in a single proceeding) while the patentholder awaits the outcome of the trial in the federal court to obtain damages.

In fact, measures under consideration within the Senate Trade Bill incorporate S. 486, introduced by Senator Lautenberg and others, which would lower some of the standards that must be met in an ITC process patent infringement investigation, such as eliminating the injury requirement. None of these proposals, however, are conceived by their advocates as being a substitute for achieving the needed modernization of the patent laws themselves that allows infringement by importation of goods made abroad using a patented process. Commissioner Quigg concurs with this view in his statements on the issue: "Although ITC proceedings are an important adjunct to enforcement of patent rights, they should not be the sole remedy available to process patentholders against competition from offshore manufacturers.[2] Commissioner Quigg has also stated:

> . . . I think it is important to keep 337, because that is a short-term compact operation which the patent owner can use to prevent the market from slipping away to foreign manufacturers. Patent litigation in the Federal courts is a more prolonged thing. It is not likely that you would be able to get a preliminary injunction during the litigation, and therefore the 337 approach does have a benefit for U.S. patentholders.[3]

It is worth noting that the ITC itself has in the past recommended that a distinction be maintained between the patent-type protection for process inventions that is sought in S. 1200 and the trade-type protection currently afforded by ITC adjudications in process patent proceedings. The Commission has asserted that its principal expertise is in micro-economic analysis of industrial competitiveness and the trade situation, factors that would not necessarily have a bearing on the pure issues of patent validity and enforcement considered in straight infringement cases before the federal courts. Some experts analyzing process patent legislation, on the other hand, maintain that the ITC remedy in its current form is adequate and the appropriate way of addressing the problem of infringing importations. They point out that ITC exercises *in rem* rather than *in personam* jurisdiction: its orders go only to the goods themselves that are being imported and used or sold here. These experts contend that this focus on the goods is fair because once the goods have passed beyond the hands of the original manufacturer, the persons handling them can no longer be assumed to be knowledgeable of the process used to make the goods. This situation differs from the analogous one involving product patents, because in a case involving product patents, the person holding the goods actually has in hand everything necessary to ascertain whether there is infringement of a patent. A comparison of the tangible item with the description and diagrams in the patent itself may well reveal an infringement. In the process patent situation, the persons holding the goods after they have left the manufacturer do not have in their hands the specific infringing element, the process by which the product was made at some point in the past, and it is not always possible to deduce the exact process that was used by an analysis of the product at hand.

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[2] "Process Patents," Hearings on S. 1543 before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks, 99th Congress, 1st Session, p.12.

[3] Ibid., p. 43.

IMPLEMENTATION OF PROCESS PATENT LEGISLATION

In approving S. 1200, the Committee rejects the view that the U.S. purchaser from an overseas manufacturer who makes goods using a process patented in the United States has no responsibility for the patent infringement involved. On the whole, it should be the burden of business entrepreneurs who purchase goods to check beforehand for possible infringement, whether of product or process patents. They do so, now in the case of product patents, and S. 1200 will encourage them to do so with respect to process patents. It is reasonable to expect that the more conscientious and legitimate importers would indeed concern themselves to a greater degree with the question of whether the goods they are importing infringe a U.S. patent, if S. 1200 is enacted, because such importers may find themselves otherwise emmeshed in litigation that may be more expensive than the importation is worth to them.

The primary target of the U.S. process patentholder will naturally be the manufacturer, who is practicing the process and importing the resulting goods into the United States. If that manufacturer is subject to the jurisdiction of the U.S. courts then it would be the preferred defendant because of its direct knowledge of the process. Since the manufacturer may not be subject to jurisdiction, S. 1200 also allows the patentholder to sue the persons receiving the goods in this country in the belief that they may be in the best position, apart from the manufacturer, to determine how the goods were made. The U.S. purchaser may protect itself in a number of ways: by specifying in the contract how the goods are to be made, or by eliciting a contractual commitment from the foreign manufacturer either to come into the U.S. courts itself to defend an infringement suit or to indemnify the purchaser against such a suit.

See also Section 2-312(3), Uniform Commercial Code (implied warranty against patent infringement).

At the same time, the Committee is sensitive to the special difficulties that may attend a charge of process patent infringement for persons who import, use or sell the products but do not themselves practice the process. The Committee is also sensitive to the concern that the bill might be abused for aggressive business purposes to harass U.S. competitors whose operations depend on importing goods from overseas. S. 1200 is intended to be a strong disincentive to the importation, use or sale of products that are made by an infringing process, but it should not simply be a weapon for patentholders to use indiscriminately to try to stop all entry of products that compete with products made by their patented process. Only goods made by an unauthorized use of the patented process should be threatened by the bill. With a view to addressing those concerns about potential abuse by patentholders, and undue burdens on defendants in actions brought under S. 1200, the Committee devised a system of damage limitations for different classes of defendants, incorporated a new procedure encouraging advance communications between process patent owners and purchasers or importers of goods in order to encourage infringement avoidance, and established a notice requirement structured to insure that the alleged infringer receives enough information to allow a reasonable assessment of whether the goods are being manufactured by a process patented in the United States.

The Committee-approved bill envisions three types of infringers:

(1) The manufacturer who uses the process without authorization who is fully liable under the bill if he engaged in importing, using or selling the resulting product in the United States.

(2) An infringing importer, user or seller who had knowledge before the infringement that a patented process was used by the manufacturer to make the product which the importer or retailer uses or sells is fully liable under the bill and is not able to utilize the modifications of damages and other remedies available under the bill for innocent infringers.

(3) An innocent (i.e. unknowing) infringing retailer or importer, user or seller who does not himself use the process, is entitled to take advantage of the limitations on damages and other remedies available under S. 1200.

As was mentioned earlier, S. 568 is the same as S. 1543 of the 99th Congress, which unanimously passed this Committee and the Senate but which failed to become enacted during the hectic closing hours of Congress last year. S. 1200 follows the same general philosophy as S. 568. In S. 568 and in S. 573, damages only lay for infringements that occurred after notice. Moreover, such damages were limited by an 18-month grace period for retailers and a 6-month grace period for non-retailers with respect to the disposal of inventory. During those time periods, damages would have been limited to reasonable royalties in order to give the notice recipient sufficient time to dispose of inventory and make rational business decisions without unnecessarily exposing himself to potentially damaging risks.

Those 6-and 18-month periods were criticized by some as "compulsory licenses." The Committee did not interpret reasonable royalties for inventory for a limited period of time to constitute even an extremely loose conception of a compulsory license. In fact, the phrase "compulsory license" implies an ongoing right of the licenses to do business in perpetuity without permission from the patent owner. Such a right has no place in U.S. patent law, and no such right was contemplated in S. 1543 or S. 568. Nevertheless, the Committee changed the legislation in order to accommodate the concerns of the parties who raise this issue. Thus, S. 1200 does not contain any such mention of time periods nor does it require any payment to the patentholder with respect to inventory disposal. Instead, S. 103(a)(2) provides that there are no remedies for infringement under this bill for product in possession, in transit to, or for which there is a binding commitment to purchase and which has been wholly or partially manufactured prior to notice of infringement.

However, if the notice recipient maintained or ordered an abnormally large amount of infringing product, the amount of product constituting the excessive inventory is subject to an infringement action. This Committee continues to believe that the aforementioned 6-and 18-month inventory provisions of S. 1543 and S. 568 are reasonable. Thus, we would encourage the courts to presume that a party who maintains or orders an amount of infringing product that cannot be used or sold after notice within 18 months by retailers or 6 months by non-retailers, is either maintaining an abnormally large inventory or is attempting to take advantage of the limitations of this bill. Such a finding would still permit the use or sale of 6 and 18 months of product without liability, but would put an infringer at risk for the amount of product in excess. Similarly, we encourage the courts to presume that the 6-and 18-month inventories are reasonable and that a party should not be subject to liability for such an inventory unless he was otherwise attempting to take advantage of this section or lost this limitation for other reasons, such as lack of good faith or actual knowledge.

Under S. 1200, a party planning to import a product which is the same as a currently produced product may make a request for disclosure to the current manufacturer. This request asks the manufacturer to list all process patents owned by or licensed to the manufacturer as of the time of the request that the manufacturer then reasonably believes could be asserted to be infringed. In the normal case, the manufacturer will respond to the request with a list of process patent numbers, and the potential infringer will use this information to advise his supplier of what processes to avoid using. Failure to present the information received from a request for disclosure to the supplier will result in a finding that the potential infringer had notice of infringement, such that remedies for infringement will be available with respect to any goods imported beyond that time.

Defending against patent infringement charges is a normal burden of doing business in America and around the world in the technologically sophisticated commercial conditions of the 1980's. The limitations on damages in S. 1200, combined with the advance disclosure procedure, should eliminate the possibility of aggressive use of process patent infringement charges to harass innocent purchasers (whether in fact infringing or not). The remedy limitation here is not to be construed as a compulsory license, nor as a precedent for other areas of patent law or types of patent infringement. The Committee finds the "grace period" policy to be justified only in the context of a bill intended to strengthen process patent protection. It is justified because of the elusive character of process inventions, from the standpoint of infringers who are involved only with the resulting products and not with the use of the process itself. From the beginning of congressional consideration of process patent reform in 1983 all proponents of the legislation have accepted the restriction of the scope of the bill to exclude innocent (i.e. unknown) infringing activity that occurs before the infringer is on notice. The remedy limitations are simply a mechanism for realizing this principle in practice by allowing the unknowing infringers, once notice is established, to sell a reasonable amount of inventory accumulated prior to notice with limitations on their exposure to damages. The temporary grace periods have as their sole purpose to allow the infringer to rid himself of products he had purchased and fulfill business commitments made prior to the time he had notice of the infringement of a U.S. process patent, and to either close down his business in this time or to find an alternative source of supply that does not infringe the patent. The remedy limitation is only available once for a given product: if the importer, wholesaler or distributor chooses to shift to a different supplier, he will be fully liable from the time of notice should the process patentholder bring another action against him with respect to the same product. Of course, the importer or retailer must be an innocent infringer, i.e. not have knowledge that the products were made by the patented process, to be eligible for the remedy limitation.

Similarly, the treatment of retailers should not be construed as an unlimited compulsory license, but as a temporary reprieve to allow them to move to non-infringing suppliers and liquidate their inventory without disrupting their businesses. Infringers fall into this category only if they obtain the illicit goods from a party in the United States who does not use the patented process. If a retailer has resources to send agents to other countries to seek suppliers, then he should be able and willing to exercise more vigilance. By using the request for disclosure procedure, he may seek out legitimate manufacturers who do not avail themselves of processes patented in this country to make products intended for export to this country. However, the Committee recognizes that in some cases, it may not be useful for retailers to avail themselves of the request for disclosure opportunity. Therefore, S. 1200 clarifies that while it is generally evidence of good faith when a party requests disclosure, the failure to request disclosure is not absence of good faith if there are mitigating circumstances. For example, for many retailers, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure may not be necessary or practicable as a means to avoid infringement. The rationale in S. 1200 is to shelter only purchasers who are remote from the manufacturer and not in the position to protect themselves in contracts with the party who is actually using the process.

While this new request for disclosure procedure will assist in avoiding intimidation of potential innocent infringers, it should be noted that the problem of using patents for illegitimate purposes of harassment is neither new nor limited to process patents. The Committee notes that the courts are not powerless to deal with the problem. For example, the federal judiciary, under Rule 11 of the revised Federal Rules of Civil Procedures, has lately taken a more stringent attitude toward an attorney's responsibility to investigate the soundness of a complaint before filing it. And the patent law itself allows the court, in an appropriate case, to order a patent owner to pay his adversary's attorney's fees and other expenses.

An additional safeguard against abuse of S. 1200 is the requirement that the notification from the patent holder charging the party with infringement must provide a specificity of information that will permit the accused party to make a reasonable business decision as to whether to continue his activities or seek a new source for the product. Notice of infringement occurs when the alleged infringer has a combination of information sufficient to persuade a reasonable person that it is likely that a product was made by a patented process. This combination of information will include actual knowledge which may be acquired from the request for disclosure procedure, the information contained in the notification from the patent holder and any other information known to the accused relevant to the issue of infringement. In issuing a notification, the patentholder must specify the patent alleged to have been used and the reasons for a goodfaith belief that such process was used. If the patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as in reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information. Thus, even if the patentholder decides to bring suit, unless his filing includes this information, he will be deemed to have served notice. Neither a vague unspecified claim of infringement, nor even a lawsuit embodying such a claim would suffice for notice of infringement; only a specific claim articulating the reasons for believing the patented process has been used, would expose the defendant to damage liability. The Committee anticipates that the difficulty of making this kind of showing will tend to discourage use of the new cause of action for the purpose of "business aggression."

Once the recipient of notice knows the exact patent or patents in question, and the reasons indicating that the process they cover was used in manufacturing the goods, he will be able to evaluate the claim, confer with the foreign manufacturer (or other supplier) and decide whether to discontinue importing goods or defend an infringement claim. The proposed notice requirements goes far beyond the norm for product patent cases (or for that matter process patent infringement cases under existing law) but the higher threshold is justified here, in the Committee's judgement, because of the special difficulties that may arise from the fact that the process was used by a party other than the defendant. The notice provision of S. 1200 is not intended as a procedent for other areas of patent protection. Despite its greater stringency, the Committee expects that the serving of notice will still fulfill its traditional role of avoiding the need for litigation in many situations.

Beside the extended notice requirement and damages limitations, S. 1200 includes two further protections for potential defendants: a grandfather clause stating that the bill shall not abridge or affect the right of any person to continue to use, sell or import products already in substantial and continuous sale or use in the United States on May 15, 1987, and a provision calling on the Department of Commerce to report annually to Congress during the first 5 years after enactment on the effect of S. 1200 on any domestic industries that submit formal complaints about interruption of legitimate sources of supply.

In reference specifically to the concerns voiced by the generic drug industry about the effects of S. 1200 on their overseas supplies, one potentially valuable resource is the Food and Drug Administration. It is the Committee's understanding that whenever a generic drug company applies for FDA approval of a new generic medicine, the FDA begins a Drug Master File (DMF) collecting among other things information from the supplier about the processes involved in generating the materials sold to and subsequently used by the generic company. The DMF is a confidential file, not available to the public or even to the generic company for inspection. The DMF is complied from information supplied directly to the FDA from the manufacturer and from inspections by FDA personnel in the factories of the manufacturer. However, if the file can be obtained by the U.S. courts under a protective order without violating any other provisions of law, it could be used to assist the court in resolving whether the patented process was used in making the goods in question. It might alleviate the need to rely on indirect forms of evidence, such as chemical analysis, to trace the process used.

The debate on the presumption clause in Section (4) of the bill goes back to the 98th Congress. At that time the Judiciary Committee reported a process patent measure without including the presumption in the text of the bill but indicating instead in the report that the Committee expected the courts to apply a presumption where warranted.[4] In the present Congress, the Committee decided to accede to the strong recommendations of the Administration and the industry advocates of the bill to include presumption in the statute itself.

The presumption would place the burden of proof on the defendant to come forward with evidence that the goods in question were not made by using the plaintiff's patented process after the plaintiff has made a reasonable but unsuccessful effort to ascertain the process actually used, and further has established a substantial likelihood that the goods were made by that process. The presumption mechanism stems from the basic principle behind the bill, that the U.S. purchaser of the goods is in the best position to make the arrangements necessary with foreign manufacturers and suppliers to assure that U.S. process patents are not violated. The Committee envisions that the plaintiff would make informal inquiries to the foreign manufacturer of the product (if identifiable) or make reasonable attempts to use the discovery procedures available in the foreign countries. Certainly, the presumption clause attempts to strike a balance. Presumptions should not be casually established. To ensure that an unfair burden is not imposed on importers and distributors of noninfringing products, any provision dealing with this subject should, at a minimum, require the patentee to demonstrate, on the basis of available evidence, that a substantial likelihood exists that the product was produced by the patented process and, further, that a reasonable but unsuccessful effort was made to determine that the process was actually used in the production of the product. To establish a substantial likelihood, for example, a patentee might show that the patented process was the only known method, or the only commercially practical method, for producing the product, or that physical evidence, such as the exact chemical composition of the product, indicates the use of the patented process. A reasonable effort requirement could easily be satisfied in the United States through our discovery procedures. For a foreign manufacturer the patentee would have to take some reasonable step, such as writing to the manufacturer, to determine how the product was made and to have been unsuccessful in this regard. The reasonableness of the effort would depend on the facts of the case but should generally avoid the need for such measures as letters rogatory or suits in a foreign country. Exactly how much evidence will be needed in particular situations to satisfy the "substantial likelihood" condition will depend on the circumstances. However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a slight possibility that the product was so made.

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[4] Senate Report 98-663, 98th Congress, 2nd Session, p. 6.

Most of our trading partners that extend process patent protection to the products made by the processes do also provide for a rebuttable presumption for shift in the process burden of proof. But many of them also limit the application of the new presumption to processes for making "new" products. The drawbacks of this approach may be illustrated by the recombinant DNA processes for producing naturally occurring substances, which cannot themselves be patented and which are in no sense "new." Thus, this approach would deprive some of the most important process innovators of the value of the presumption. The Committee rejects this approach because there is no clear justification for discriminating against certain types of process inventions. In order to secure a patent, a new process must be deemed useful, novel and unobvious—the same criteria that are applied to product inventions. If a process invention satisfies these criteria, then it is in the interests of society to have it publicly disclosed in return for a limited period of exclusivity for the inventor, regardless of whether the process leads to a "new" or "old" product. A good example of the latter was presented to the House Judiciary Committee during a hearing on this issue by Genentech Corporation; a new, more economical process they have developed in conjunction with Lubrizol Corporation for producing Vitamin C.[5] Enactment of S. 1200 would help Genentech protect itself against an influx of Vitamin C produced abroad by means of their economical new process, and produced all the more cheaply because the foreign manufacturer had no R&D expenses in procuring the process. But under the "new product" approach, Genentech would not benefit from the presumption clause in bringing suits for such infringement of its process.

Most of the foreign patent statutes that extend process protection to the product resulting from the process also include the limitation that the product must be made "directly" from the process. The significance of this qualification is discussed at length in the section-by-section analysis. The basic point is that if a final product has undergone a material change after being initially produced by the patented process, then it should no longer be covered within the scope of protection offered by S. 1200.

Some parties urged the Committee to include the word "directly" in the statutory language of the bill, making the U.S. law conform to the norm of industrialized nations and insuring that process patent protection does not become too broad. A number of industry advocates of the bill on the other hand were concerned that including the word "directly" might unduly restrict the scope of the bill if it were interpreted narrowly to exclude products that had been altered in trivial ways after the stage of manufacture where the patented process was used. The Committee concluded that both parties were seeking the same balance, and reached the decision to exclude products that had been "materially changed by subsequent processes; or . . . become a trivial and nonessential component of another product." Inevitably the courts will have to assess the permutations of this issue of proximity to or distance from the process on a case-by-case basis. The section-by-section analysis offers guidance and examples for the interpretation of this provision.

Because of our obligations under the GATT treaty to refrain from trade discrimination, the process patent bill was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product was made (and the process used) in this country or in a foreign country. As explained earlier, the bill is prompted by the use of patented processes in other countries followed by the importation of the resulting products into this country. The use of the process in this country is already an act of infringement under existing patent law, and such an infringing party would be subject to the jurisdiction of the U.S. courts. Thus the inclusion of domestic process patent infringement in the scope of a bill to extend protection to the products is regarded by the Committee as a formality to conform to the GATT, with little or no practical consequences in patent enforcement. The American Bar Association suggested in a letter to the Committee[6] that an alteration should be made in the presumption clause to make clear that if a suit is brought under the bill against a purchaser of goods made domestically by infringing a process patent, then the presumption is not applicable since there is no obstacle to obtaining discovery to determine the process used to make the goods. The Committee accepts the ABA's reasoning that the presumption should not be operative in this situation, but concludes that no change in the language of the bill is necessary. The presumption would never apply in the situation of domestic process patent infringement because a reasonable effort on the part of the plaintiff would require obtaining discovery against the manufacturer who is actually practicing the process in this country and who is therefore subject to the U.S. courts' jurisdiction, as might not be the case with foreign manufacturers. In any case, the Committee does not expect or intend the bill to be used to sue purchasers of the product, when the infringing manufacturer can be sued instead.

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[5] Statement of Thomas D. Kiley, Esq., Vice President, Corporate Development, Genentech, Inc., before the House Judiciary Subcommittee on Courts, Civil Liberties and the Administration of Justice, February 19, 1986 (Hearing on "Intellectual Property and Trade." 99th Congress, Serial Number 60).

[6] Letter from Jan Jancin, Jr., President, ABA Section of Patent, Trademark and Copyright Law, to Senator Mathias, March 10, 1986. Printed in "Process Patents," Hearing on S. 1543 before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks, 99th Congress, 1st Session, pp. 266-8.

Concerns were raised, at a Senate hearing and elsewhere, that process patent legislation would undermine the Drug Price Competition and Patent Term Restoration Act, which became law in the 98th Congress (P.L. 98-417). Generally, this law combined an expedited procedure for FDA approval of generic imitation on brand-name drugs. The generic companies contended that if their supply of raw materials from overseas sources is reduced by process patent infringement suits, then the goals of P.L. 98-417 would be undermined. With the protections built into the substitute approved by the Committee, the generic pharmaceutical industry now supports S. 1200. It should be recognized, in particular, that the grandfather clause gives an exception for the many new generic medicines that have been approved or whose applications have been submitted to the FDA during the period between enactment of P.L. 98-417 (signed into law on September 24, 1984) and May 15, 1987.

Once the patent on a brand-name drug has expired, anyone is free to make, use or sell the product (assuming FDA clearance), but if there is an unexpired patented process for making the drug, then other parties must find a different way to make it. Again, in order to obtain a patent, the process must be novel, useful and unobvious, an invention whose disclosure would benefit the public as envisioned in the Constitution. To obtain a process patent on a useful, new way to make a medicine is not to prolong or "evergreen" the product patent on the medicine itself, even if the patentholder for the process and original product is the same inventor. No responsible critic of S. 1200 has ever maintained that goods made abroad by a process patented in the United States should be allowed to come into the United States to benefit competitors of the process patent-owner. To the extent that this is happening at present, S. 1200 is indeed intended to cut off such lines of supply, and to expose the beneficiaries, after adequate notice, to damage liability for their actions. The only issue has been whether the bill could also be used to cut off other, legitimate supplies from overseas, and in response to this concern the Committee has fashioned an elaborate system of pre-disclosure safeguards and limitations.

D. SECTION-BY-SECTION ANALYSIS

SECTION 101

Section 101 amends Section 154 of title 35, United States Code, by adding to the present rights held by the patent owner, the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by a patented process.

SECTION 102

Section 102 amends Section 271 of title 35, United States Code, by adding a new subsection (g). This subsection provides that whoever without authority imports in the United States or sells or uses within the United States a product which is made by a process patented in United States is liable as an infringer.

Since a process patentee can already prevent the use of the patented process by domestic manufacturers, the primary effect will be on foreign-made goods. These amendments will not give extraterritorial effect to U.S. law. U.S. patents will not prevent foreign manufacturers from using abroad the process covered by the U.S. patent, so long as the products they make thereby are sold and used abroad. But the amendments will prevent circumvention of a U.S. process patentee's rights through manufacture abroad and subsequent importation into the United States of products made by the patented process.

Specifically, the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs." See 271(e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

The bill provides that no remedy may be granted for infringement resulting from the noncommercial use or retail sale of a product unless there is no adequate remedy on account of the importation or other use or sale of that product. The purpose of this provision is to protect retail sellers and the consumers who purchase products at retail for personal use and consumption from damages for infringement if adequate relief is obtainable from more involved parties.

The Committee intends the limitations on remedies against "noncommercial users" to be for the protection of those purchasers who enjoy personal use and consumption of the product produced by the allegedly infringing process, such as the patient who consumes a drug product or a home gardener who sprays a pesticide. The Committee does not intend this protection to be enjoyed by a party who uses a product produced by an allegedly infringing process in the production of another product, or who otherwise engages in further manufacturing, processing, or other industrial or business use of the product, other than that which may fall under the provision of Sec. 287(b)(2).

It should be noted that many of the "products" produced by patented biotechnology processes are themselves "used" in the manufacture of another product which is introduced into commerce. Consider a process patent held on a method for preparing a plasmid or other vector. The use of the plasmid or vector to insert a new gene into a living cell, instructing the cell to produce an important human protein (such as insulin or interferon) which will then be separated from the fermentation mash, purified, and packaged into single dosage forms, is a commercial use and is ineligible for the limited protection granted to non-commercial uses. The field of biotechnology is particularly susceptible to commercial "uses" without sales. For example, a patent may cover a process for producing a microorganism using recombinant DNA technology. The microorganism is then used to produce a particular commercial end-product of great value. The bill's provisions limiting remedies against users are not intended to apply to such commercial uses. The Committee believes that without expeditious remedies against use-based infringement, merely stopping importation and non-retail sale of the microorganism after its entry into the country fails to prevent commercial use of the microorganism.

An understanding of the statement that "A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product" is critical to understanding the scope of this legislation. The Committee intends a specific two-phase test to be implemented.

Many foreign patent statutes extending process protection to the product resulting from the process include the limitation that the patented product be made "directly" from the process. They use the word "directly" to exclude as an infringement the importation, use or sale of a product which is materially changed from the product resulting from the patented process by subsequent steps or processes. An example of the problem the Committee is addressing in this section is the extraction of minerals from the earth. These minerals may later be used to manufacture materials, which are still later embodied in components, which are in turn used in the assembly of the product in question. In this instance, the minerals have been "materially changed" within the meaning of this section.

The Committee agrees that once a product has been materially changed, then subsequent purchasers, users and sellers should no longer be liable for process patent infringement. However, the Committee decided against including the word "directly" in the statute out of concern that the word "directly" might have been construed too broadly and possibly exempt too many products that have been altered in insignificant ways after manufacture by the patented process. These products ought to be treated as infringing under the bill. The Committee expects the courts to exercise careful judgement in distinguishing those products that are too far removed from the patented process, and those that have been changed only in insignificant ways. The Committee believes that the courts will be in a better position to settle such issues without the standard of "directly" constraining their judgment.

The inclusion in the standard of the words "trivial and nonessential component" will further assist the court in distinguishing products that are too far removed from the patented process.

In order to give the courts Congressional guidance in what may be a difficult determination, the Committee notes that the bill would establish the following two-phased test:

1. A product will be considered made by the patented process regardless of any subsequent changes if it would not be possible or commercially viable to make that product but for the use of the patented process. In judging commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.

2. A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in a manner which changes the basic utility of the product by the patented process. However, a change in the physical or chemical properties of a product, even though minor, may be "material" if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually, a change in the physical form of a product (e.g. the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a "material" change.

It is only those who import, use or sell a product after it has been materially changed or has become a trivial or nonessential component of another product who may avoid liability for process patent infringement. Even with that general guidance, the courts may frequently find themselves in a quandary on this most important phrase. There will be cases where the product has clearly been materially changed or become trivial and nonessential, under the two-phase test, and others where it clearly has not; however, many instances will be less clear. Some examples may help provide additional resources to the courts:

A metal strip with certain unique properties is produced by a U.S. patented process. A foreign competitor makes the strip using the process, then turns the strip into a core, puts the core in a transformer and imports the transformer into the United States. Even if there were other commercially or economically viable noninfringing processes for making the strip, this is still a clearcut case of infringement of the process patent that this Act is intended to prevent because the subsequent changes would not be considered material. Similarly, taking that metal strip and hear treating or annealing it in a magnetic field would not change the product as to avoid infringement.

If the patented process produces chemical X, any person importing, using or selling chemical X is liable for infringement.

If new entity, chemical Y, is produced from chemical X as the result of a material change, the court must also consider the other phase of the test before deciding if Y is infringing or non-infringing:

If the only way to have arrived at Y is to have used the patented process at some step, e.g., producing X as an intermediate, Y is infringing.

If there is more than one way to have arrived a Y, but the patented process is the only commercially viable way to have done so, Y is infringing.

If there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product having satisfied both phases of the test.

In the biotechnology field it is well known that naturally occurring organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence. A foreign manufacturer uses the patented process to prepare the DNA molecule which is the product of the patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vecot containing the DNA molecule is, inturn, inserted into a host organism; for example, a bacterium. The plasmid-containing host organism still containing the specific genetic sequence undergoes expression to produce the desired polypeptide. Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the product will be considered to have been made by the patented process.

In the semiconductor industry, a manufacturer may have a process patent for forming a semiconductor structure in a semiconductor substrate. Subsequent processing to complete and finish the component does not materially change the semiconductor substrate in which the semiconductor structure formed. In addition, a court could determine that the cost of a semiconductor component was trivial in relation to the cost of the whole product, but if that same component is essential to the intended function of the whole product then it would be covered by this title.

The Committees recognizes the concern raised concerning possible overreach. One example is a process patent for extracting minerals from the earth. There is no intent that the minerals, eventually refined, with the product ending up as a component of an automobile which is imported into this country, should subject the importer to an infringement action. However, this must be distinguished from the importation of the mined minerals themselves. Similarly, this must be distinguished from the case wherein the patent covers a process for making shock absorber. Even if that shock absorber is put into a much larger and more expensive product, e.g., an automobile, the patent owner could still sue the importer of that automobile. Although injunctive relief might not be appropriate under those circumstances, some damage relief would be appropriate, based, for example, on an apportionment of the contribution of the infringing part to the value of the whole product in which it is incorporated. Of course, the importer and wholesaler have other rights under this bill to limit liability, and the retailer may avail himself of other provision of this bill and have no liability for retail sales. Finally, there is no intent whatsoever for the innocent consumer to even be subject to suit.

SECTION 103

Section 103 amends Section 287 of title 35 by adding a new subsection (b) with five subparagraphs, which introduces limitations on the remedies available to a process patentholder when infringement is based on importation, sale or use of a patented process and conditions associated with the eligibility of the modification of remedies.

Paragraph (b)(1) provides that the modification of remedies outlined in subsection (b) are not available to three categories of infringers. For these three categories of infringers, all of the provision of title 35 relating to damages and injunctions apply. Paragraphs (b)(1) (A) through (C) define those infringers who are not entitled to any diminution of the monetary and injunctive remedies normally available to a patentholder. They include the party who actually carries out the process, or who controls or is controlled by that party. Thus, those who are closely connected with carrying out the process in the manner outlined, are fully liable for any direct acts of infringement they commit in the United States, as well as for any acts of inducement of infringement or contributory infringement committed through control inside or outside the territorial limits of this country. The bill is not intended to reward infringers who close their eyes to facts that a reasonable person would see. Similarly, it is not intended that a party should be permitted to qualify for reduction of or immunity from liability by intentionally avoiding the acquisition of knowledge.

Existing section 287 of title 35 states that damages for patent infringement may be recovered by the patentholder either from the time he marks his patented article with the patent number, or if he fails to mark, from the time he serves notice to the infringer. However, the courts have held that these prerequisites for damages apply only to product patents, and that persons who infringe a process patent by using the process in this country are fully liable from the beginning of the activity without notice from or marking by the patent owner. The Committee intends that this harsher standard apply also with respect to process patent infringers who use the process and engage in importing, using or selling the products in the United States. This would apply in a situation, for example, where a foreign manufacturer who uses a process patented in the United States but not in the country of manufacture, itself imports the products for use or sale here. In that situation, the foreign manufacturer would be liable for damages from the outset of the infringing activity even without receiving notice of infringement from the patent owner. Similarly, any party who knowingly imports, uses or sells products made without authority by a process patented in this country is fully liable for damages running from the time he begins knowingly engaging in such activity. On the other hand, a foreign manufacturer is not liable under the bill if he merely uses the process abroad (again assuming the U.S. inventor has not also patented the process in the foreign country) and sells the product there with no knowledge that the buyer will subsequently import the product here.

Paragraph (2) specifies that with regard to infringers not excluded under paragraph (1), the patentholder has no remedy for infringement with respect to any product which was in the possession of, or in transit to the party, of for which the party has made a binding commitment to purchase and which has been partially or wholly manufactured before the party had notice of infringement. The Committee intends that with respect to an infringer not excluded under paragraph (1), the patentholder has no remedy for infringement with respect to pre-notice inventory. However, if the court finds that the party maintained or ordered an abnormally large amount of infringing product, or the product was acquired or ordered by the party to take advantage of the limitation on remedies provisions, the court shall limit the application of the modification of remedies provisions to the reasonable portion of the inventory. For the purpose of this paragraph, an abnormally large inventory on hand or on order shall be presumed to exist if it cannot be sold in the normal course of the infringer's business in 18 months if the infringer is a retailer or in 6 months in any other case. Thus, courts should presume that maintaining or ordering an amount of infringing product that cannot be used and sold after notice of infringement within 18 months by retailers and 6 months by non-retailers is either maintaining an abnormally large inventory or an attempt to take advantage of the limitations of this bill. Such a finding would still permit the use or sale of 6 and 18 months of product without liability, but would put an infringer at risk for the amount of product in excess. Similarly, the Committee encourages the courts to presume that the 6 and 18 month inventories are reasonable and that a party should not be subject to liability for such an inventory unless he was otherwise attempting to take advantage of this section or lost this limitation for other reasons, such as lack of good faith or actual knowledge.

Paragraph (3) provides that in an action brought for infringement under section 271(g) of title 35, United States Code, the court shall take into consideration the good faith and reasonable business demonstrated by the defendant, the good faith demonstrated by the plaintiff with respect to the request for disclosure discussed below, and the need to restore the exclusive rights of the patentholder through an adequate remedy.

During the discussions and testimony leading to the adoption of this bill, the non-manufacturing groups likely to use or sell imported products stressed their need and desire to obtain information to assist them in avoiding infringement. A procedure to assist these groups in attaining this information is necessary because an importer of a product from a foreign manufacturer is ordinarily unable to obtain specific information from his supplier regarding the process used in manufacturing the imported product. The groups representing patentholders agreed to a procedure under which manufacturers would provide a listing of the patent numbers of process patents owned by or licensed to the manufacturer as of the time of the request that the manufacturer then reasonably believes could be asserted to be infringed in connection with the production of its product.

The request for disclosure procedure is explained in paragraph (4). The first step—the actual request for information is a formal request made by a party who is engaged in, or intends to become engaged in, the sale of a particular product. The request is directed to one or more other parties who are then engaged in the manufacture of the product, no the expectation they are most likely to hold pertinent process patents. Such a request should be made before the requester actually commences any activity which could result in infringement, and it should be made in all cases except those in which, because of the nature of the product, the number of parties to whom a request would need to be directed, or like circumstances, a request for disclosure would be impracticable or unnecessary. For example, due to the nature of the product or the number of sources for products, it may not be practicable for retailers to use this procedure to avoid infringement.

An illustration of the situation in which a request would be impracticable would be one in which a party intends to import a table that is simple and undistinguished, and the party knows that similar tables are made by many other companies. Since requests would have to be directed to a large number of companies and there is nothing unusual about the table to be imported, a request for disclosure is very unlikely to produce meaningful information. It is impracticable. However, if the subject table had a distinctive construction, and a similar one was being manufactured by only a few companies, the importer would be expected to request disclosure.

A request for disclosure is unnecessary when the party who would otherwise make it already has the information sought, for example, when a prior request was previously made to the same source and it is clear no additional patents have arisen since the earlier request. Of course, a court should be reluctant to conclude that a request was "unnecessary" when, in fact, the product is found to be made by an infringing process, and a request for disclosure might have avoided the infringement.

The second step in the procedure is the patentees's response to the request. The patentee is expected to provide a complete good faith response, identifying all process patents owned by or licensed to him that he reasonably believes could be used to make his own product. It is understood that the patentee's response will depend largely on the information available to him at the time the request is made. For example, it is also possible that the manufacturer may acquire additional relevant patents subsequent to the request for disclosure. The manufacturer is not precluded from making, indeed is encouraged to make, supplemental responses if the acquisition of additional information warrants it.

The request for disclosure must include a representation by the requesting party that it will submit the response to its manufacturer, or if not known, to its supplier, with the request for assurance that none of the processes of the disclosed patents is used in the manufacture of the product.

The requirement of "notice of infringement" embodied in various paragraphs of subsection (b), is intended to balance the interests of process patentees and parties who are infringing by using or selling the product, in good faith, without knowledge of the process used to produce it. The Committee does not intend that "notice" be a device through which infringers can escape liability by deliberately avoiding knowledge or failing to appreciate the significance of information available to them. What should be kept in mind is that no liability attaches in any event unless infringement of the patentee's rights has occurred: "notice" simply defines the point in time when someone who is, in fact, an infringer has sufficient information to make it reasonable to initiate the period of his accountability.

As stated in subparagraph (5)(A), the accumulation through actual knowledge, or receipt by a party of a written notification, or a combination thereof, of information will put the infringer on notice when, in the aggregate, it is sufficient to persuade a reasonable person that it is likely a patented process was or is being used. It is important to note that the issue to be resolved with respect to "notice of infringement" is not whether there are sufficient facts recited in the notification or known to the party notified to support the conclusion that there is infringement but rather only whether infringement is "likely." This is significantly less demanding than the "preponderance of evidence" standard a patentholder would face in proving infringement at trial. What is required is simply enough to bring home to the infringer the presence of an appreciable likelihood of infringement, sufficient to make it reasonable to hold him accountable when he chooses to continue his activities.

Subparagraph (5)(B) relates to written notification addressed to the accused infringer by the patentholder. The written notification shall specify the patented process that is alleged to have been used and the reasons supporting a good faith belief that such process was used. If the patentholder has actual knowledge of other commercial processes for producing the particular product, the notification should set forth such information with respect to such processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

Subparagraph (C) provides that a party who receives a written notification of infringement shall be deemed to have notice of infringement if he fails to seek responsive information from the manufacturer (or, if not known, the supplier) of the product he is using or selling, unless there are mitigating circumstances. The notification need only meet the first sentence of subparagraph (B) to trigger that requirement and that result; obviously it is unnecessary to provide the manufacturer with information tending to negate the use of other processes, since the manufacturer knows directly what process he is using. Similarly, this provision applies even though the notification does not contain enough information to constitute "notice of infringement."

A non-manufacturing party receiving a notification alleging infringement has an obligation to take reasonable steps to determine if there is any basis for the allegation and cannot evade liability by remaining ignorant of facts which might establish a likelihood of infringement. Any knowledge which a purchaser may acquire as a result of such inquiries will contribute to satisfying "notice of infringement," which can be satisfied by a combination of the information contained in a notification from the patent holder and any other information known to the party charged with infringement.

Since making an effective inquiry is not costly, and it has the potential of stopping, curtailing or avoiding infringement of the patent holder's rights, only the most compelling reasons should be accepted as excusing a failure by the recipient of a notification to submit it to his manufacturer/supplier for verification. An example of such "mitigating circumstances" would be death or incapacity of the person who was intended to make the submission or an inability to locate the manufacturer/supplier due to his no longer being in business or in circumstances where the product has passed through many hands.

For similar reasons, subparagraph (D) provides that a party who receives a response to a request for disclosure and who fails promptly to submit it to the manufacturer/supplier with a request for a written statement that none of the patented processes is used, is deemed to have notice of infringement. Submission of the response to a request for disclosure to the requester's manufacturer/supplier is mandated because that manufacturer knows the process being used and therefore is in the best position to avoid infringement or provide evidence that the patented process is not being used, if that is the case.

The mere act of submitting the patentee's response or notification to the manufacturer does not, however, automatically absolve a party from having notice of infringement. The Committee has not attempted to, and could not, spell out in detail all circumstances in which the infringer should be found to have notice. Nevertheless, the Committee expects the court to consider, in determining the presence or absence of notice, the information received (or lack thereof) by the importer from his manufacturer/supplier. For example, a party who sends to his manufacturer/supplier a notification of infringement or a response to a request for disclosure, and who does not receive from that manufacturer/supplier an adequate assurance that the patented process is not being used, and sufficient supporting information to make an assurance credible should almost certainly be found to have notice of infringment should he choose to continue to deal in the goods of that supplier/manufacturer.

Subparagraph (E) provides that filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A), i.e. contain sufficient information to persuade a reasonable person that it is likely the product was made by a patented process. The Committee recognizes, however, that it may not always be clearcut when sufficient information exists to constitute "notice of infringement", and that patentholders may properly and lawfully bring suit irrespective of whether that technical requirement is met. Neither "notice of infringement" nor "notification" is a prerequisite for a legally sufficient complaint for patent infringement.

Even if "notice of infringement" is not satisfied by the initial papers filed in the action, this subparagraph recognizes that it may be satisfied at a later time by other papers filed in the action, including discovery obtained from the accused infringer or third parties, additional information provided by the patentholder, expert witness statements or the like. As discussed earlier, remedies for infringement will not begin to accrue until the standard for notice of infringement is met, even if a legal action has already begun.

SECTION 104

Section 104 adds a new Section 295 to title 35, to establish in carefully defined circumstances, a rebuttable presumption that a product that could have been made by use of a patented process was in fact so made. This presumption addresses the great difficulties a patentee may have in proving that the patented process was used in the manufacture of the product in question where the manufacturer is not subject to the service of process in the United States. The burden of overcoming this presumption will be on the alleged infringer, regardless of whether the infringement charge is based on use, importation, or subsequent sale of the infringing article. While the defendant may not necessarily have in its possession the means necessary to rebut the presumption, it is likely to be in a far better position than the patentee to obtain them. Importers, for example, because of their relationships with foreign manufacturers, may be able to exert pressure on such manufacturers to produce the necessary information. Users and sellers who purchase possibly infringing articles from importers may be able to exert similar pressure on those importers, who would in turn influence foreign manufacturers. Of course, purchasers would retain whatever rights to indemnification they may have under contract or applicable State law.

Presumptions of manufacture by a patented process, however, should not be casually established. Importers and subsequent purchasers may be unable to obtain the information needed to overcome such presumptions when the products in question were not made by patented processes. At a minimum, the existence of the presumption will require a party who uses, sell, or imports a product that might have been made by a patented process to exercise greater care in business dealings to avoid increased liability. To minimize the risk of aggressive litigation intended to discourage firms from carrying competing products, the presumption will be available under Section 295 only when two conditions are satisfied.

First, the patentee must demonostrate on the basis of the evidence that is available that a 'substantial likelihood' exists that the product was made by the patented process. Such evidence could include chemical analysis of the product or indications or "marks" on the product itself, as well as expert testimony regarding known methods of production at costs that would justify sale of the product at the prices being charged. Exactly how much evidence will be needed in particular situations to satisfy the "substantial likelihood" condition will depend on the circumstances, However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a slight possibility that the product was so made. Second, the patentee must show that he or she has made a reasonable effort to determine what process was used in the manufacture of the product in question and was unable to do so. The reasonableness of the effort would include the use of discovery procedures under the Federal Rules of Civil Procedure or other good-faith methods, such as requesting the information from the manufacturer, if not subject to U.S. jurisdiction. These limitations on the availability of the presumption should make it available to patent owners who might otherwise be left with no remedy against an infringer, and should also adequately safeguard the rights of competitors.

The Committee notes that the rebuttable presumption would be inapplicable if the defendant has used the process in the United States, or has derived the products directly or indirectly from a manufacturer who used the process in the United States. In these circumstances, the discovery provisions of the Federal Rules of Civil Procedure and the equitable powers of Federal courts should be sufficient to allow the plaintiff to ascertain what process was employed. In this regard, the Committee trusts the courts to issue protective orders, in appropriate circumstances to prevent disclosure of the trade secrets and confidential business data of the parties. For example, the Committee expects protective orders to be used in encouraging foreign manufacturers to supply information pertinent to a process patent infringement suit revolving around goods made by such manufacturers. If information is obtained under a protective order that definitely determines the process used to make the goods in question, the presumption, would not be applicable.

Once the plaintiff has been found to be entitled to the presumption, the burden of producing evidence to establish that the product was not made by the process shifts to the defendant. Courts will continue to determine which party has the ultimate burden of persuasion and what amount of proof is necessary.

SECTION 105

Section 105(a) contains a grandfather clause exempting commercial arrangements that have been or were about to be entered into prior to May 15, 1987. The special importance of this provision for the generic pharmaceutical industry was mentioned in the Statement. Since the Drug Price Competition and Patent Term Restoration Act of 1984, over 100 abbreviated new drug applications (ANDA's) for generic medicines have been approved by the FDA. The Committee firmly believes it would be inequitable if process patent legislation were to interfere with the marketing of these newly approved generic drugs, or with other ANDA's that were pending but not yet approved on May 15, 1987, if substantial commercial investments had been made in them prior to that date.

That is, if a generic pharmaceutical company has made substantial commercial investment in preparing and filing an ANDA and is awaiting FDA approval as of May 15, 1987, or if the company had been granted an approval before that date and starts to market a generic medicine in the United States, the pharmaceutical products that the company imports, uses and sells in connection with the ANDA are protected under the grandfather clause. The generic company may expand or contract its business with these products, shift to different suppliers as necessary and continue to come under the protection of the grandfather clause.

Apart from this particularly sensitive area, the Committee envisions that the courts will interpret the scope of the grandfather clause in the individual cases brought before them with a view to the qualifying language "to the extent equitable" in the provision. Ordinarily, a party whose business before the grandfather date involved infringing activity should be able to continue to import, use or sell the product as necessary to maintain the same level of business, but not to expand such business by increasing the volume of products that he is using or selling, unless of course he has prospectively committed himself to such increases in a contract made prior to the grandfather date.

An important variation of this restriction could be illustrated as follows. If an importer contracts prior to May 15, 1987 to receive a certain volume of goods every month for the next 5 years, and a certain retailer contracts to purchase the goods from him during that period, both of these arrangements fall within the grandfather clause exempting them from the scope of the bill. If the retailer only contracts to purchase the goods for 3 years and the importer turns to another retailer afterwards, again the bill should not apply to the second retailer during the remaining 2 years of the importers contract, even though no contract with the second retailer existed prior to May 15, 1987, because the goods in question were contracted for by the importer before that date. However, if in this situation, the importer expands the volume of the goods he is importing, then the grandfather clause does not exempt him with respect to units beyond what he contracted for before the grandfather date.

In addition, the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of a drug. See Sec. 271(e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

The Committee intends to provide the courts with flexibility to achieve an equitable solution in situations where the infringer has made a substantial investment necessary to sell or use the infringing product before this date. In that case, the investment was made during a time when use or sale of the product was not unlawful. The grandfather clause is modeled after 35 U.S.C. 252, and Section 107(d) of P.L. 98-662 (98 Stat. 3384) which Congress has provided for fundamentally the same purpose.

The Committee intends three other restrictions on the scope of the grandfather clause. The phrase "successors in business" does not include parties to whom the grandfathered infringer may license the goods; the phrase is meant only to allow the infringer who sells his business to pass on also its grandfathered status to the buyer of the business.

Secondly, the grandfather clause does not apply to any business whose product had already been the subject of International Trade Commission litigation before January 1, 1987. The Committee has included the grandfather exception for those parties who reasonably relied upon the law as it was when they made their investments so that they should not be penalized for such good faith reliances and should be allowed, to the extent equitable, to recoup those investments made in the United States. However, when the product has already been the subject of ITC litigation, there are no good faith reliances since the patent owner has already indicated his clear intention to enforce his process patent in any and all appropriate forums, and investments therefore occur at the alleged infringer's own risk. It is not the Committee's intention to deny patentholders the right to pursue process patent infringement actions in U.S. courts against alleged infringers who made commercial investments during the prosecution of the ITC suit.

Thirdly, the grandfather clause applies to products being purchased, imported, used or sold as part of an ongoing business operation before the grandfather date only with respect to the process of manufacture used at that time to make such products. If the manufacturer of the products later shifts to a different process, such as a process developed and patented in the United States well after the grandfather date which the manufacturer in question has not been authorized to use, then units of the product made by this latter process are not protected by the grandfather clause, even if the U.S. wholesaler, importer or distributor had contracted with the manufacturer before the grandfather date for continued supply of the product. In order to keep products under the umbrella of the grandfather clause while fulfilling such a contract, the manufacturer would have to make them by the process contemplated at the time of contracting (or May 15, 1987). This example, incidentally makes plain that importers, wholesalers and distributors who come under the grandfather clause with respect to some product still would have a strong incentive to make a request for disclosure to all manufacturers in the United States who are marketing that same product in order to insure their eligibility for the remedy limitations in the event that their supplying manufacturer shifts to a different process at some point in the future and so disengages the protection of the grandfather clause.

Section 105(b) makes clear that the bill does not affect any remedies patent owners have under existing law. The new remedies for process patent owners provided by the bill are subject to general limitations which do not apply in suits under existing law by process patent owners against parties manufacturing in the United States. For example, the bill requires notice of infringement to persuade a reasonable person that it is likely that the product was made by a patented process. The bill limits remedies available with respect to products already in the possession of or in transit to the infringer, or which the infringer already has made a binding commitment to purchase. The bill encourages parties to request disclosure of the identity of certain process patents. The bill provides that a product which is made by a patented process will not be considered so made after it is materially changed by subsequent processes; or it becomes a trivial and nonessential component of another product. there is no intention to impose any of these limitations on owners of product patents or on owners of process patents in suits they are able to bring under existing law. Neither is there any intention for these provision to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.

SECTION 106

Section 106 instructs the Department of Commerce to report annually to Congress on the effect of the bill on any U.S. industries that submit formal complaints that they have lost legitimate sources of supply. Such reports will assist Congress in the unexpected event that the bill has a drastic adverse effect on some domestic industry, requiring emergency remedial measures.

IV. TITLE II—PATENT MISUSE DOCTRINE REFORM

A. Purpose of Amendment

As amended, title II of S. 1200 provides that a patent owner's licensing practices cannot be found to constitute patent misuse unless such practices violate antitrust laws.

B. History of Legislation

Legislation was first introduced in the 98th Congress (S. 1841, title IV) to reform the patent misuse doctrine as part of the administration's National Productivity and Innovation Act. Hearings on the bill reflected extensive support of and no opposition to title IV: the chairman of the ABA Patent Law Section, the president of Intellectual Property Owners, Inc. and the president of the American Intellectual Property Law Association supported enactment of title IV. *Patent Law Improvements Act, 1984, Hearings on S. 1535 and S. 1834*, before the Senate Committee on the Judiciary, 98th Congress, 2d Sess. 44, 52, 91, 105 (1984). However, concern over the specific language of the proposal was expressed and, ultimately, the Congress went on to approve and enact only title I of the bill as the National Cooperative Research Act of 1984 (the so-called "Joint R&D Venture Bill"), Public Law 98-462.

In the 100th Congress legislation was again introduced to reform the law of patent misuse. S. 635, Section 115, 100th Congress, 1st Sess. General patent law oversight hearings were held by the Subcommittee on Patents, Copyrights and Trademarks, and testimony received during those hearings again supported enactment of patent misuse reform legislation.

In a statement submitted for the record by Ronald T. Reiling on behalf of Digital Equipment, Reiling highlights the need for misuse legislation in the current technological age:

> These misuse doctrines are inappropriate to this era when intellectual property rights are essential components of technological and economic growth and international competitiveness. The current misuse doctrines hinder development and distribution of technological advances by requiring only that a court fine "some" anticompetitive effect.

Reiling's observations are echoed in a statement submitted to the Subcommittee on Patents, Copyrights and Trademarks by Robert

Kline, President of the American Intellectual Property Law Association. In a letter dated June 4, 1987, Kline outlines the AIPLA concerns with the current doctrine:

> The "misuse" doctrine is a counterproductive legal fiction. It negatively affects virtually every license agreement involving technology developed or used in the United States. The doctrine reduces the incentive to innovate. This doctrine does not increase or stimulate competition.

Kline continues by detailing improvements in S. 1200:

> S. 1200 is a clear and straight forward solution to the "patent misuse" problem. It would merely require and ensure that economic analysis has been conducted before a court would be able, properly, to refuse to enforce a valid patent on anti-competitive grounds.

During Subcommittee consideration of S. 635, a proposal was made to change the language listing specific conduct by patent owners to which the law would apply to a more generic and easily applied approach that had been recommended in earlier testimony by the AIPLA witness. Chairman DeConcini adopted this amended language in an original bill circulated to the Subcommittee, and, on May 13, 1987, the Subcommittee unanimously approved that bill, containing the present title II on reform of the misuse doctrine. This original bill was then introduced by Chairman DeConcini on May 14, 1987 as S. 1200. *See* Cong. Rec. S6480-86 (May 14, 1987 daily ed.)

The Committee on the Judiciary met and considered the bill on June 4, 1987, and voted favorably to report the legislation. The Committee intends by adoption of this bill to clarify the law of patent misuse and to put intellectual property rights on an equal footing with other property with respect to license, sale, and other agreements concerning the distribution of property rights.

C. Discussion

The doctrine of patent misuse is a judicially created doctrine. It constitutes a defense to a patent infringement suit and provides that a patent owner may not enforce its patents if it has engaged in conduct deemed "misuse," at least until the patentee's conduct constituting misuse has ceased and its effects purged. Misuse thus renders the patent unenforceable, not void.

One branch of the misuse doctrine involves conduct alleged to constitute fraud on or inequitable conduct before the Patent Office. This part of the doctrine remains unaffected by title II.

The second branch of the misuse doctrine, to which this legislation is addressed, has its root in judicial interpretations that find misuse present because of alleged anticompetitive extensions of the owner's patent rights. For example, while misuse may be found where the antitrust laws have been violated, it may also be found where the patent owner's conduct has not violated the antitrust laws, has not demonstrated anticompetitive effect, and has not even injured the infringing party who raises misuse as a defense.

In recent years the need for reform of the law of patent misuse has gained increasing recognition. Commentators have repeatedly criticized the doctrine, and reform was initially proposed in title IV of S. 1841, the National Productivity and Innovation Act, introduced by Senator Thurmond in the 98th Congress. Hearings on this earlier proposal revealed extensive support for reform of the patent misuse doctrine.

In 1984 hearings before the Subcommittee on Patents, Copyrights and Trademarks, Bernarr R. Pravel of the American Intellectual Property Law Association (AIPLA) testified that reform of the law of patent misuse would encourage and promote the efficient use of newly created technology. Mr. Pravel stated:

> Very often, the creators and owners of advances in technology in the form of intellectual property are not able to fully develop its commercial applications. In these cases, the most effective, and often the only, method of bringing this technology to the market place is for its owner to license it to another with the ability to do so. However, despite the practical benefits of licensing to the industrial innovation process, courts have sometimes found intellectual property licensing practices to be unlawful without fully considering the effect of the practices on competition.

Recent statements by the U.S. Department of Justice and American Bar Association Section of Antitrust Law also emphasize the need for reform. In a letter to the Subcommittee on Patents, Copyrights and Trademarks dated June 4, 1987, John R. Bolton, Assistant Attorney General of the U.S. Department of Justice, stated that:

> The Department believes that legislation in the misuse area is both important and timely, and thus strongly support this legislation. Because the sanction of misuse is harsh . . . patent owners can be expected to avoid entering into patent licensing arrangements that they fear may be deemed to constitute patent misuse. In order to reassure creators of new technology that the courts will not interfere with procompetitive patent licensing, the misuse doctrine must not be applied in a manner that condemns competitively desirable licensing.

Robert P. Taylor of the American Bar Association Section of Antitrust Law stated in a letter to the Subcommittee of May 11, 1987, that:

> This change is needed to promote and encourage the licensing of new technology. In many situations, the misuse doctrine in its present form forces the owner of new technology to choose between either not licensing at all or licensing under circumstances which place at risk the enforceability of his property and contractual rights to that technology . . . It also means that creative and innovative licensing schemes are rarely if ever used, because any license provision that is even slightly questionable is likely to place the entire patent at risk whenever an enforcement proceeding is brought.

Some courts have themselves questioned the soundness of the patent misuse doctrine. The Justice Department has urged its reform: Deputy Assistant Attorney General Roger Andewelt articulated a firm foundation for concluding that the misuse doctrine has been applied in a manner inconsistent with sound economic principles in his speech before the Bar Association for the District of Columbia on November 3, 1982. And recent law review commentary has condemned certain applications of the misuse doctrine as inherently anticompetitive. 46 U. Pitts. L. Rev. 209 (1984).

The lack of clarity and predictability in application of the patent misuse law doctrine and that doctrine's potential for impeding procompetitive arrangements, are major causes for concern. Title II addresses this concern by providing that conduct shall only be found to be misuse when that conduct violates the antitrust law. As Donald W. Banner of the organization Intellectual Property Owners, Inc. observed in his 1984 testimony before the Subcommittee, the proposed reform would "add predictability to the law governing licensing practices" and "eliminate a hodgepodge of arbitrary rules developed by courts during the era when courts were hostile to licensing." Mr. Banner continued: "By providing more certainty to the permissible scope of licensing practices, the bill would increase the value of patents to patent owners. This would strengthen the incentives that patents provide to engage in research and development."

ORIGIN AND DEVELOPMENT OF THE PATENT MISUSE DOCTRINE

Patent misuse is a judicially created doctrine that allows a patent owner's overextension of his or her patent rights to be asserted as a defense in an action by the patent owner to enforce the patent. If the patent owner is held to have overextended, or "misused" patent rights, equity may bar the owner from enforcing the patent as long as the misuse continues. *Morton Salt Co.* v. *G.S. Suppiger Co.*, 314 U.S. 488 (1942).

The doctrine of patent misuse originally emerged as a judicial response to the patent owner's practice of conditioning the sale or license of patented inventions upon the purchase or license of additional products. This practice was at first approved by courts, including the United States Supreme Court. In *Henry* v. *A.B. Dick Co.*, 224 U.S. 1 (1912) the Court upheld a patent owner's practice of requiring, as a condition to sale of a patented invention (mimeograph machine), that the invention be used only with certain supplies (ink) provided by the patent owner.

By 1917, however, the Court's attitude had changed. Citing the enactment of Section 3 of the Clayton Act as evidence that such conditional sales were against public policy, the Court held that the conditions to sale were unenforceable regardless of whether they violated the Clayton Act. In *Motion Picture Patents Co.* v. *Universal Film Manufacturing Co.*, 243 U.S. 502 (1917), the owner of a patent for a film feeder used in the projection of motion pictures sought to license the feeder on the condition that the licensee show only films leased from persons approved by the patent owner. The patented film feeder was dramatically superior to other film feeders on the market, giving the patent owner significant market power. The Court refused to enforce the patent, finding that imposing the condition would extend the patent owner's power beyond the scope of its patent rights. *Id.* at 518.

Cases following *Motion Picture Patents* continued to expand the doctrine of patent misuse. In the *Morton Salt Co.* case, where the term "patent misuse" appears for the first time, the Supreme Court held that the misuse defense was available even to a person who knowingly infringed a valid patent and was not affected by the conduct held to be misuse. The patent owner in *Morton Salt* had licensed its patented sale machine upon the condition that the licensee use the machine with salt tablets purchased from the patent owner. According to the Court, this use of the patent exceeded the limited grant of the Patent Act, the patent owner had misused the patent, and the owner therefore was not entitled to the protection of the Act. 314 U.S. at 491. The Court found it unnecessary to determine whether the patent owner's action had violated the antitrust law. 314 U.S. at 494.

In *Morton Salt,* as in *Motion Picture Patents,* the Court ignored the antitrust issues presented and based its decision on public policy grounds. From this origin courts have developed the principle that a claim of patent misuse need not be supported by a showing of violation of the antitrust laws. *See, e.g., Zenith Radio Corp.* v. *Hazeltine Research, Inc.,* 395 U.S. 100, 140–41 (1960); *Duplan Corp.* v. *Deering Milliken, Inc.,* 444 F. Supp. 648 (D.S.C. 1977), *aff'd* in relevant part, 594 F.2d 979 (4th Cir. 1979). In most courts, the *Morton Salt* principles, interpreted as they were in *Zenith Radio* and *Duplan,* remain the established law of patent misuse. See Section of Antitrust Law of the American Bar Association, Antitrust Law Developments (2d) 488–89 (1984), and cases cited therein.

Recently, however, the Seventh Circuit challenged the reasoning of *Motion Picture Patents, Morton Salt,* and the line of cases following these decisions. In *USM Corporation* v. *SPS Technologies, Inc.,* 694 F.2d 505 (7th Cir. 1982), *cert. denied,* 462 U.S. 1107 (1983), the court of appeals, in dicta, questioned whether the reasoning of *Motion Picture Patents* accurately characterized the economic effect of practices held to constitute patent misuse. At issue in *USM Corporation* was whether the inclusion of a different royalty schedule in a license agreement constitutes patent misuse. Citing the facts of several prior findings of patent misuse, including *Brulotte* v. *Thys Co.,* 379 U.S. 29 (1964) (patent license extending licensee fees beyong license period), *Zenith Radio Corp.* v. *Hazeltine Research, Inc.,* 395 U.S. 100, 133–40 (1969) (patent royalties measured by the sale of unpatented products containing the patented item), and *Stewart* v. *Mo-Trim, Inc.,* 192, U.S.P.Q. 410 (S.D. Ohio 1975) (licensees required not to make items competing with the patented item), Judge Posner noted that:

> As an original matter one might question whether any of these practices really "extends" the patentee. The patentee who insists on limiting the freedom of his purchaser or licensee . . . will have to compensate the purchaser for the restriction by charging a lower price for the use of the patent. . . . True, a tie-in can be a method of price discrimination. It enables the patent owner to vary the

> amount he charges for the use of the patent by the intensity of each user's demand for the patent. . . . But since . . . there is no principle that patent owners may not engage in price discrimination, it is unclear who one form of discrimination, the tie-in. alone is forbidden.

Id. at 510–11.

In addition, the *USM Corporation* court questioned the appropriateness of the law showing of anticompetitive effect required to establish patent misuse. The court suggested that patent misuse claims could be tested under standard antitrust principles, stating that, "Our law is not rich in alternative concepts of monopolistic abuse and it is rather late in the day to try to develop one without in the process subjecting the rights of patent holders to debilitating uncertainty. *Id.* at 512.

D. SECTION-BY-SECTION ANALYSIS

Subsections (1) and (2) provide for conforming changes to Section 271 of title 35, United States Code. Subsection (3) provides for the addition of language to Section 271 addressing patent misuse. This language provides that no patent owner shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices, actions or inactions relating to his or her patent, unless such conduct violates the antitrust laws.

The term "patentowner" is intended to include all persons with the rights commonly held by a patentowner, including a licensee of a patent who is engaged in the sublicensing of the patent.

Title II includes contributory infringement as well as infringement, to make clear that a party charged with contributory infringement under 35 U.S.C. § 271(c) must also show conduct violating the antitrust laws to support the affirmative defense of patent misuse.

The reference to "illegal extension of the patent right" as well as "misuse" recognizes the differing formulations of activity deemed to be "misuse" and that misuse is often characterized as illegal extension of the patent right. Such reference to "illegal extension" is not meant, by itself, to alter or expand in any way the existing law of patent misuse.

The terms "licensing practices," "actions," and "inactions" are intended to include omissions as well as affirmative acts. The refusal to license or failure to take action is intended to be included within the meaning of "licensing practices or actions or inactions."

The broad reference to the patentowner's "actions or inactions relating to his or her patent"—in addition to "licensing practices"—indicates that the provisions of the subsection are not limited in application to licensing practices, but extend to all actions taken by the patentowner with respect to his patent, including the sale of patented products as well as the license of patent rights. The phrase "actions or inactions relating to his or her patent" includes the patentowner's sale of a product that embodies the patent.

E. JUSTICE DEPARTMENT VIEWS

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF LEGISLATIVE AND INTERGOVERNMENTAL AFFAIRS,
Washington, DC, June 4, 1987.

Hon. DENNIS DECONCINI,
Chairman, Subcommittee on Patents, Copyrights and Trademarks, Committee on the Judiciary, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: In response to your request, the Department of Justice has reviewed the patent misuse title of S. 1200, a bill to amend title 35, United States Code. This title would clarify and reform the doctrine of patent misuse. It is similar in purpose and effect to pending legislation introduced on behalf of the Administration as part of its overall trade and competitiveness package (S. 539), and separately introduced by Senators Thurmond and Cochran as part of S. 635. The patent misuse title of S. 1200 would prohibit the courts from depriving patent holders of their exclusive property rights in their inventions because of alleged misuse of these rights unless their conduct violates the antitrust laws. The Department believes that legislation in the patent misuse area is both important and timely, and thus strongly supports this legislation.

Misuse is a judicially created doctrine founded in the courts' equitable powers. It frequently is used to attack patent licensing practices that are alleged to be undesirable from a public policy standpoint. Because the sanction for misuse is harsh—for example, a patent is unenforceable against anyone until the misuse has ceased and its effects purged from the marketplace—patent owners can be expected to avoid entering into patent licensing arrangements that they fear may be deemed to constitute patent misuse. In order to reassure creators of new technology that the courts will not interfere with procompetitive patent licensing, the misuse doctrine must not be applied in a manner that condemns competitively desirable licensing.

Unfortunately, misuse has been applied as a per se doctrine prohibiting conduct that careful analysis demonstrates is not necessarily anticompetitive and, in fact, often is procompetitive. Reform of the misuse doctrine is needed: Congress should make clear that licensing practices may be condemned as misuse on competitive grounds only if sound antitrust analysis demonstrates that those practices are indeed anticompetitive.[1]

Title II of S. 1200 states simply that "No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions, in view of the circumstances in which such practices or actions are employed, violate the antitrust laws."[2] The Administration's proposal is to the same effect, but would go into more detail by listing five specific types of practices related to patent licensing that could not be the basis for a finding of misuse unless such conduct, in view of the circumstances, violated the antitrust laws. It would also require any other allegation that a patentee had misused its rights by "otherwise [using] the patent allegedly to suppress competition" to be evaluated under antitrust law standards.

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[1] While reform of the misuse doctrine to track antitrust analysis would have substantial benefits, improvements in the manner in which intellectual property licensing arrangements are considered under the antitrust laws are also crucial to encouraging innovation and productivity. Congress has before it proposals for improvements in this area, including a proposal of the Administration (see S. 438, H.R. 557, S. 539, S. 635). We hope that legislation in the misuse area will be accompanied by passage of such complementary legislation.

We also support the inclusion in S. 1200 of legislation clarifying licensor and licensee rights in the event of licensee challenge to patent validity.

Title II of S. 1200 would appear to accomplish the same result as the Administration's more detailed proposal. Both would make clear that licensing conduct may not be condemned as misuse on grounds related to competition unless analysis under antitrust standards demonstrates such conduct to be anticompetitive.[3] Accordingly, should Congress decide to take the more generalized approach embodied in Title II of S. 1200, the Department would enthusiastically support the legislation.[4]

We very much appreciate your interest and efforts in reporting legislation designed to encourage the development of new technologies by ensuring that procompetitive patent licensing is not unreasonably discouraged by the misuse doctrine. If we can be of further assistance in this regard, please feel free to call on us.

The Office of Management and Budget has advised this Department there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

JOHN R. BOLTON,
Assistant Attorney General.

V. TITLE III—LICENSEE CHALLENGES TO PATENT VALIDITY

A. PURPOSE OF AMENDMENT

As amended, title III of S. 1200 provides that a licensee cannot be estopped from challenging the validity of a patent to which it is licensed. It further provides that the parties to a licensing contract may define their respective rights regarding termination of a license and payment of royalties if the validity of the licensed patent is challenged.

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[2] This new language would constitute 35 U.S.C. § 271(d). Existing subsections (c) and (d) of that section would be redesignated as paragraphs (c)(1) and (c)(2) respectively.

[3] Title II is virtually identical to language suggested to the Subcommittee in 1984 by the American Intellectual Property Law Association (AIPLA). AIPLA noted that its suggested language "would not alter existing law with respect to the misuse doctrine as it applies to improper practices not related to competition (e.g., fraud on the Patent and Trademark Office and the like)." Supplemental Statement of Bernarr R. Pravel, President, AIPLA. Before the Subcommittee on Patents, Copyrights and Trademarks, Committee on the Judiciary, United States Senate, April 23, 1984, on S. 1841 (Titles III and IV) at 6–7. The Administration's proposal similarly would not alter existing law with respect to such practices.

[4] We understand that you intend to conform the language of proposed new section 271(d) by adding the words "or inactions" after the word "actions" where they do not already appear. By requiring an antitrust evaluation of licensing practices or actions or inactions relating to a patent, the legislation would make quite clear that neither licensing nor refusals to license could be condemned as misuse absent a finding of an antitrust violation. "[Refusal] to license the patent to any person" is one of the specific types of practices listed in the Administration's proposal. See section 115 of S. 635.

B. History of Legislation

Legislation to address the concerns surrounding challenges to patent validity was introduced in the 98th Congress in S. 1535, a bill to amend title 35, United States Code, to increase the effectiveness of the patent laws and for other purposes. It would have allowed either the licensee or the licensor to terminate the license once the licensee asserts invalidity in a judicial action. However, the licensee would have had to continue to pay royalties directly to the licensor unless the license was terminated. Upon termination by either party, further unlicensed practice of the patented invention would subject the former licensee to the infringement provisions of the patent laws.

During hearings held before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks (Serial No. J-98-107, 4/3/84) then Assistant Secretary and Commissioner of Patents and Trademarks, Gerald Mossinghoff, agreed that a clarification of the *Lear* decision was needed:

> A fairer balance between the rights of licensor and those of the licensee is needed without compromising the public interest. New section 295(b) proposed by section 10 would achieve this balance with a number of straightforward principles. Either the licensor or the licensee could terminate the license once the licensee asserts invalidity in a judicial action. However, the licensee would have to continue to pay royalties directly to the licensor unless the unlicensed practice of the patented invention would subject the former licensee to the infringement provisions of the patent laws.

However, at that time, Commissioner Mossinghoff also noted the need for some changes in the legislation:

> We believe the statute should not be drafted in the form of section 10, which would increase Federal interference in patent licensing. We believe the correct approach is to do exactly the opposite. Parties should be properly able to negotiate contracts containing provisions, for instance, that a licensor or licensee could terminate if the licensee challenged the validity of the license in a judicial proceeding.

Though S. 1535 was approved by the Judiciary Committee, it was not ultimately enacted into law.

Former Chairman Mossinghoff's suggestions were included in Title III of an original bill circulated by Chairman DeConcini to members of the Subcommittee on Patents, Copyrights and Trademarks. On May 13, 1987 the Subcommittee unanimously approved this bill containing Title III on the reform of licensee challenges. This original bill was then introduced by Chairman DeConcini on May 14, 1987 as S. 1200. See Cong. Rec. S. 6480-06 (May 14, 1987 daily ed.).

The Committee on the Judiciary met and considered the bill on June 4, 1987, and voted favorably to report the legislation.

C. STATEMENT

Since the United States Supreme Court decision in *Lear* v. *Adkins*, 395 U.S. 653 (1969) there has been considerable uncertainty in the area of patent license validity. In particular, there has been confusion as to the rights of licensees and licensors in a patent license agreement where the validity of the patent is challenged in litigation. Numerous law review articles have been written in an attempt to sort out the case law including *Unmuzzling the Patent Licensee: Chaos in the Wake of Lear* v. *Adkins*, 59 J. Pat Offic. Society 475 (1977).

In the *Lear* case, an inventor, Adkins, alleged breach of a patent licensing agreement against the licensee, Lear. Lear then challenged the validity of the patent and refused to pay royalties. In this case, the Supreme Court overturned the licensee estoppel doctrine and assured a licensee the right to challenge the validity of the patent. The Court recognized the public interest in freedom from invalid patents and that the licensee is the party most able and most likely to challenge validity.

Prior to *Lear*, a licensee was precluded from questioning the validity of any patent under which it was licensed, i.e. license estoppel. The theory underlying this doctrine is that a licensee should not be permitted to enjoy the benefit afforded by the agreement while simultaneously urging that the patent is void. However, the result of *Lear* was that the licensee was able to attack patent validity under conditions competitively unfair to the licensor. For example, a licensee can negotiate the best license terms available, accept a contract, and then question patent validity without relinquishing the license.

Under the current case law, the following hypothetical could occur. The licensee negotiates successfully with the patent owner for the right to practice the patented invention. A royalty is agreed upon. The licensee then brings a declaratory judgment action against the patentowner to have the patent declared invalid. The court allows the licensee to pay the royalties owing into an escrow account during the pendency of the case. If the patent is declared invalid, the licensee continues to use the invention and retain the royalties paid into the escrow account. If the patent is declared valid, the licensee continues to use the invention; he has not breached the license agreement so the patentowner has no ground to prevent it. The patentowner receives the royalties from the escrow account but these are royalties already owing under the license. The licensee risks nothing and stands to lose nothing, except attorneys fees, in this situation.

In a statement before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks during its February 17, 1987 General Oversight Hearing on Patent and Trademark Law, American Intellectual Property Law Association President, Robert Kline highlighted these problems:

> The unfairness of the current state of the law is especially relevant when the licensor is an individual inventor and the licensee is a large corporation. This is often the case and was in *Lear*. If a patent owner does not have the resources to utilize his invention, he must license it to an-

> other who possesses those resources. That licensee is able to bear the cost of litigation where the licensor is often hardpressed to do so.

As this explanation illustrates, the patent owner is in a no win situation. If the licensee has the exclusive right to use the invention, during the legal challenge the patent owner is deprived of all royalty income during this period.

D. SECTION-BY-SECTION ANALYSIS

Section 1 of this title adds a new section with two subsections to Chapter 29 of title 35, United States Code. Subsection (2) provides that a licensee shall not be estopped from asserting the invalidity of a patent to which it is licensed, and that any provision in an agreement between the parties that purports to bar such an assertion shall be unenforceable. Thus, it codifies the holding of *Lear* v. *Adkins* that a licensee cannot be estopped, by agreement or otherwise, from contesting the validity of a patent to which it is licensed.

Subsection (b) provides that a patent license agreement may contain provisions allowing temination if the licensee challenges its validity in a judicial proceeding. It further provides that if the licensee has a right to terminate, the agreement also may provide for the licensee's obligations under the agreement to continue until the patent is finally declared invalid or until the license is terminated. Under the subsection (b) such provisions will be enforceable as long as they are consistent with federal patent law or policy.

This issue, namely, the rights of the parties with respect to termination of a license and payment of royalties if the licensee challenges the validity of the licensed patent is one over which courts have differed in the years since the *Lear* decision. New section 295(b) would give the parties broad discretion to define these rights during the license negotiation process. It makes clear that the parties may provide for termination by licensor and-or licensee in the event of such a challenge, and, if the licensee has a right to terminate, for the licensee's obligations to continue pending adjudication of validity. In this way, patent licensors can bargain for provisions they feel necessary to assure the realization of their rights in an invention, while licensees can bargain for provisions they feel necessary to protect their interests if they choose to challenge patent validity.

Subsection (b) also clarifies the issue of whether it is equitable to allow the parties to agree that the licensor should receive royalties during litigation which results in the patent being held invalid. Some courts have interpreted *Lear* to require that royalties owing during the period of litigation should not go to the licensor after a finding of invalidity. The Court of Appeals for the Federal Circuit (CAFC) *Cordis Corporation* v. *Medtronics, Inc.* 780 F.2d 991(1985) held, inter alia, that *Lear* does not provide authority for courts to establish escrow accounts to hold royalty payments until after the case has been decided. The CAFC did not decide the issue of whether royalties paid after the complaint in a case in which the patent was held invalid should be returned to the licensee or retained by the licensor. The CAFC cited *Nebraska Engineering Corp.* v.

Shivvers 557 F2d 1257, (8th Cir.1977) as standing for the proposition that royalties paid after the complaint may have to be returned to the plaintiff. A more thorough explanation of the equities surrounding this issue is found in *REC Corporation* v. *Applied Digital Systems Inc., RCA Corporation* v. *Hazeltime Corp., Lear Siegler* v. *RCA Corporation,* 217 USPQ 241 (Dist. Ct. Delaware 1983):

> The opinion in the *Lear* case does not reach the issue which is presented here: when a licensee elects to pay royalties while litigating the validity of the patent, he may, if successful, recover those royalties. I conclude "no". When a licensee continues to pay royalties after filing a declaratory judgment action, it does so because it believes that course is in its best interest. As Prof. McCarthy has pointed out, a licensee "hedges" its bet by continuing the payment of royalties aned thereby continues to derive benefits from the license even while attacking the patent. McCarthy, *"Unmuzzling" the Patent Licensee: Chaos in the Wake of Lear* v. *Adkins,* 59 J. Pat. Off. Socy 475, 528–33 (1977). First, the license assures that the licensee will be able to continue its use of the patented invention during the litigation and, if it loses, thereafter. It has neither of these assurances if it chooses to cease paying and terminate the license. Moreover, continued payment assures the licensee that its use pendente lite and thereafter, if he is unsuccessful, will be at the license royalty rate, thereby providing insurance against the possibility of a higher court determined "reasonable royalty" or a higher negotiated rate in a new license. Finally, continued payment provides insurance against the possibility of an award of attorney's fees or treble damages in the event the challenge of the patent is unfruitful. Given the fact that the licensee reaps these benefits from the payment of royalties under the license while litigating, I believe equity is on the side of the patentee when recoupment is sought after a finding of patent invalidity. Moreover, I perceive no inconsistency between a result consistent with this equity and the policy considerations which underlie *Lear.* Since I find no special circumstances favoring recovery of royalties by Lear Siegler, judgement will be entered for RCA on this claim.

The Committee believes that subsection (b) settles the issue in an equitable manner by allowing an agreement between a licensee and licensor to stipulate that royalty payments shall continue until a final determination of invalidity is reached or until the license is terminated.

VI. TITLE IV—PHARMACEUTICAL PATENT TERM RESTORATION ACT AMENDMENTS

A. Purpose of Amendment

As amended, title IV of S. 1200 extends the patent on the pharmaceutical product gemfibrozil for a period of 5 years.

B. STATEMENT

The Committee believes that patent term extension is extraordinary relief, but that the circumstances surrounding gemfibrozil are sufficiently unique to warrant extension. Further, the Committee believes that this action will set no precedent justifying the extension of patents on other drug products.

The unique circumstances involving gemfibrozil are as follows. First, gemfibrozil was approved by the Food and Drug Administration (under the brand name "Lopid") in 1981 for the limited claim of treating triglycerides among adult patients with a risk of pancreatitis, but approval was contingent upon a Phase IV study involving effectiveness and long-term safety. At the time, Warner-Lambert, the patent holder, was engaged in a primary heart attack prevention study conducted by the Helsinki Heart Council in Helsinki, Finland. (Finland has the highest death rate from coronary disease.) The 1981 approval by the FDA specified that "satisfactory completion of the ongoing Finnish study" would meet the Phase IV study requirements. Without the additional study, gemfibrozil could not have been marketed for any purpose.

Second, the Finnish study was more extensive and would take longer than any previous Phase IV study. It involved basic medical research and endeavored to establish the basic medical hypothesis regarding cholesterol that raising the level of high density lipids helps protect against arteriosclerosis and heart attacks. Warner-Lambert financed the double-blind study, which was administered by officials of the Helsinki Heart Council.

Third, after the Finnish study was begun, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Act") was introduced and enacted. That legislation changed the regulatory environment for human pharmaceuticals. At the time of the 1981 FDA approval, Warner-Lambert reasonably expected at least five more years of market exclusivity for Lopid following the expiration of its patent on July 4, 1989. Enactment of the Act affected the period of market exclusivity for Lopid. Title IV restores the minimum period of protection that Warner-Lambert could have reasonably expected in 1981 and does so in a manner that eliminates any precedential value.

C. SECTION-BY-SECTION ANALYSIS

Section 1 of this title amends Title 35 of the United States Code.

Subsection (a) of section one adds a new section 155B entitled "Patent Term Restoration," which section is divided into two subsections.

Subsection (a) of new section 155B extends for five years the patent on a composition of matter which is a "new drug" if five conditions are met.

First, the composition which is covered by the patent must have been subjected to a regulatory review by the Federal Food and Drug Administration (FDA).

Second, such composition must have been approved by the FDA in a new drug application after the receipt of a letter from the applicant stating that the Phase IV clinical study requested by the agency as a condition of approval of the composition has been undertaken.

Third, the Phase IV study must have covered at least five years. This means that the period which elapsed from the time the first patient entered in the study (i.e.), the commencement of the study term) until the last patient completed the study (i.e., the ending of the study term) was at least 5 years. For example, in the case of gemfibrozil, the Phase IV study began when the first patient entered the study on November 3, 1980, and ended when the last patient completed the study on March 21, 1987. In addition, the Phase IV study must have been commenced prior to the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984 and ended subsequent to the enactment of that Act. The Drug Price Competition and Patent Term Restoration Act of 1984 was introduced as S. 1538 on June 23, 1983 and ultimately became Public Law 98-417 of September 24, 1984.

Fourth, the Phase IV study must be completed and a supplemental new drug application (NDA) to expand the permitted indications and usage in the labeling of the new drug based upon such Phase IV clinical study must have been submitted to the FDA. The requirement of an expansion of the indications and usage of the composition is satisfied by any change in the permitted "indications and usage" section of the existing package insert of the drug, as those terms are defined in 21 Code of Federal Regulations 201.57(c), reflecting a decrease in the incidence of morbidity or mortality for hyperlipidemic patients as shown by the results of the Phase IV study.

Finally, the supplemental NDA must either have been approved or, if the FDA has not made a final determination as to the approvability of the application, the patent must be within ninety days of expiration.

If the patent is extended because the FDA has not made a final determination regarding the approvability of the supplemental NDA prior to ninety days before the patent expires, the patent extension shall immediately terminate if the FDA subsequently makes a final determination disapproving the supplemental NDA.

Subsection (b) of new section 155B requires the holder of the rights to the patent of a qualifying drug to inform the Commissioner of Patents of the number of the patent covering the composition. The notification must take place within the earlier of:

—30 days after enactment of the section if approval of supplemental NDA occurs before enactment of this section;
—30 days after the approval of the supplemental NDA if such approval does not occur before enactment of the section; or
—Between the 90th and 60th day prior to the expiration of the patent if the FDA has not made a final determination as to the approvability of the application before the 90th day prior to expiration.

Upon receipt of such notification from the patent holder, subsection (b) of new section 155B then requires the Commissioner of Patents to issue a certificate of extension for the qualifying composition of matter patent. The certificate of patent extension must be recorded in the official file of the patent extended and is to be considered part of the original patent. In the case of a patent extension granted on the basis that the FDA had not made a final determination as to the approvability of the application, the subsection requires the holder of the rights to the patent to notify the Commission of patents within 2 days if the FDA makes a final determination to disapprove the supplemental NDA. This provision would not be invoked by the customary interim FDA letters saying that the supplemental NDA is incomplete or unapprovable without further information or labeling changes, but would be invoked if the FDA states with finality that the supplemental NDA is disapproved for lack of proof of effectiveness.

Upon receipt of such notification, the Commissioner must promptly issue a certificate of termination of extension, stating that the patent extension is terminated as of the date of the FDA's disapproval of the supplemental NDA as a final agency action. Such certificate of termination must be recorded in the official file of the patent extension terminated.

Subsection (b) of section 1 amends the title to read as follows:

> A bill to amend title 35, United States Code, with respect to patented processes, patent misuse, license challenges to patent validity, and patent term restoration.

VII. REGULATORY IMPACT STATEMENT

In compliance with paragraph 11(b), Rule XXVI of the Standing Rules of the Senate, the Committee has concluded that no significant additional regulatory impact would be incurred in carrying out the provisions of this legislation; there would not be additional impact on the personal privacy of companies or individuals; and there would be no additional paperwork impact.

VIII. COST OF LEGISLATION

U.S. Congress,
Congressional Budget Office,
Washington, DC, June 15, 1987.

Hon. Joseph R. Biden, Jr.,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed S. 1200, the Process Patent Amendments Act of 1987, as ordered reported by the Senate Committee on the Judiciary, June 5, 1987. Based on information from the Patent and Trademark Office, CBO estimates that enactment of this bill would not result in significant additional costs to the federal government and will not affect the budgets of state or local governments.

Title I of S. 1200 would extend to patent owners the right to exclude others from using or selling in the United States, or importing into the United States, a product made by a patented process. If this bill is enacted, the holder of a process patent would be allowed, with certain restrictions, to seek damages for patent infringements. After certain court findings, the product would be presumed to have been made by a patented process, and the burden of proving otherwise would fall on the alleged infringer. The bill would also require the Secretary of Commerce to submit to the

Congress annual reports for five years on the effectiveness of the amendments included in Title I.

Title II provides that no patent owner can be denied relief for infringement because of his or her licensing practices or actions, unless such practices or actions violate the antitrust laws. Title III declares unenforceable any agreement between the parties to a patent license agreement that would prevent the licensee from asserting the invalidity of a patent. Title IV establishes procedures for restoring the term of patents for certain new drugs by extending their term for five years.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,

Sincerely,

EDWARD M. GRAMLICH, *Acting Director.*

IX. CHANGES IN EXISTING LAW

In compliance with paragraph 12, Rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 1200, as reported, are shown as follows (new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

TITLE 35, UNITED STATES CODE

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PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

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CHAPTER 14—ISSUE OF PATENT

Subsection 154. Contents and Terms of Patent

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling, the invention throughout the United States, *and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,* referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof.

* * * * * * *

Subsection 155B. Patent Term Restoration

(a) Notwithstanding section 154 of this title, the term of a patent which encompasses within its scope a composition of matter which is a new drug shall be extended for a period of 5 years, and such patent shall have the effect as if originally issued with such extended term, if—

(1) such composition has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act,

(2) the Federal Food and Drug Administration has approved a new drug application after receipt of a letter from the applicant stating that a Phase IV clinical study that had been requested as a condition for approval has been undertaken,

(3) the Phase IV clinical study has covered at least 5 years with the study term commencing prior to the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984 and ending subsequent to the enactment of such Act,

(4) such Phase IV clinical study has been completed, and a supplemental new drug application to expand the permitted indications and usage in the labeling of the new drug based upon such Phase IV clinical study has been submitted to the Federal Food and Drug Administration,

(5) the Federal Food and Drug Administration has either approved the supplemental new drug application or the original patent term is within 90 days of expiration, and

(6) the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved.

If, however, the term of a patent is extended because the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved prior to 90 days before the expiration of the patent, such patent extension shall immediately terminate if the Federal Food and Drug Administration makes a final determination disapproving the supplemental new drug application.

(b)(1) The patentee, his heirs, successors, or assigns shall notify the Commissioner of Patents and Trademarks within 30 days after the date of enactment of this section, or within 30 days after the date of the approval of the supplemental new drug application if such approval does not occur before enactment of this section, or within 30 days after the date which is 90 days from the expiration of the original patent term if the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved by such date, of the number of the patent to be extended.

(2) On receipt of such notice, the Commissioner shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter to which such extension is applicable. Such certificate shall be recorded in the official file of the patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office. If, subsequent to a notification that it is within 90 days of the expiration of the patent and that the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved, a final determination is made by the Federal Food and Drug Administration that the supplemental new drug application is disapproved, the patentee, his heirs, successors, or assigns shall, within 2 days, notify the Commissioner of

Patents and Trademarks of such final determination. On receipt of such notice and if the patent has been extended pursuant to the terms hereof, the Commissioner shall promptly issue a certificate of termination of extension, under seal, stating the fact that the patent is terminated, effective the date of the final determination that the supplemental new drug application is disapproved, and identifying the composition of matter to which such termination of extension is applicable. Such certificate shall be recorded in the official file of the patent terminated and such certificate shall be considered as a part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

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CHAPTER 28—INFRINGEMENT OF PATENTS

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Subsection 271. Infringement of Patent

(a) * * *

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(c)*(1)* Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(2) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions or inactions, in view of the circumstances in which such practices or actions or inactions are employed, violate the antitrust laws.

(e) * * *

* * * * * * *

(g) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer,

if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes;

(2) it becomes a trivial and nonessential component of another product.

CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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Subsection 287. Limitation on Damages *and Other Remedies;* Marking and Notice

(a) Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 105 of the Process Patent Amendments Act of 1987. The modifications of remedies provided in this subsection shall not be available to any person who—

(A) practices the patented process;

(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.

(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to the party, or which the party has made a binding commitment to purchase and which has been partially or wholly manufactured, before the party had notice of infringement as defined in paragraph (5). The party shall bear the burden of proving any such possession, transit, binding commitment, or manufacture. If the court finds that (A) the party maintained or ordered an abnormally large amount of infringing product, or (B) the product was acquired or ordered by the party to take advantage of the limitation on remedies provided by this paragraph, the court shall limit the

application of this paragraph to that portion of the product supply which is not subject to such a finding.

(3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider—

(i) the good faith and reasonable business practices demonstrated by the defendant,

(ii) the good faith demonstrated by the plaintiff with respect to the request for disclosure as provided in paragraph (4), and

(iii) the need to restore the exclusive rights secured by the patent.

(B) For purposes of subparagraph (A), the following are evidence of good faith: a request for disclosure by a party, a response by the party receiving the request for disclosure within 60 days, and submission of the response by the party who received the disclosed information to the manufacture, or if not known, the supplier with a request for a written statement that the process claimed in the disclosed patent is not used. The failure to perform any such acts is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances shall include the case in which, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

(4) For purposes of paragraph (3), a "request for disclosure" means a written request made to a party then engaged in the manufacture of a product to identify all process patents owned by or licensed to the party as of the time of the request that the party then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request—

(A) made by a party regularly engaged in the United States in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products in the United States;

(B) made prior to such party's first importation, use, or sale of units of the product produced by an infringing process and prior to notice of infringement; and

(C) which includes a representation by the requesting party that it will promptly submit the patents identified to the manufacturer, or if not known, the supplier of the product to be purchased by the requester, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

(5)(A) For the purpose of this subsection, notice of infringement means actual knowledge, or receipt by a party of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a patented process.

(B) A written notification from the patent holder charging a party with infringement shall specify the patent alleged to have been used and the reasons for a good faith belief that process was used. If the

patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

(C) A party who receives a written notification as described in the first sentence of such subparagraph (B) and fails to thereafter seek information from the manufacturer, or if not known, the supplier, as to whether the allegations in the notification are true shall, absent mitigating circumstances, be deemed to have notice of infringement. This provision shall apply even though the notification does not establish notice of infringement under subparagraph (A).

(D) A party who fails to make the submission referred to in subsection (b)(4)(C) shall be deemed to have notice of infringement.

(E) Filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A).

Subsection 295. Presumption: Product Made by Patented Process

In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds—

> *(1) that there is evidence establishing a substantial likelihood that the product was made by the patented process, and*
>
> *(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.*

Subsection 296. Licensee Challenges to Patent Validity

(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent for which the licensee has obtained a license. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

(b) Any patent license agreement may provide for a party or party or parties to the agreement to terminate the license if the licensee asserts, in a judicial action, the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached or until the license is terminated. Such agreement shall not be unenforceable as to such provisions on the grounds that such provisions are contrary to Federal law or policy.

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